UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
/ MAGISTRATE JUDGE BRUCE E. REINHART

CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT

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Pursuant to Pretrial Order ("PTO") No. 31, and this Court's Orders [DE 2513, 2515, 2716, and 2720], Plaintiffs file this Consolidated Medical Monitoring Class Action Complaint on behalf of themselves and all others similarly situated, against the defendants named herein ("Defendants"), and seek equitable relief to remedy the harms caused by Defendants' unlawful design, testing, manufacture, marketing, packaging, labeling, handling, distribution, storage, and/or sale of over-the-counter ("OTC") and prescription ranitidine-containing medications, including those sold under the brand name Zantac (collectively, "Ranitidine-Containing Products"). Plaintiffs' allegations are based upon personal knowledge as to Plaintiffs' own conduct, investigation of counsel based on publicly available information, and the limited discovery conducted to date.

I. INTRODUCTION

Zantac is the branded name for ranitidine, a drug that was touted and sold for nearly four decades as a safe and effective heartburn and indigestion drug. Zantac and other Ranitidine-Containing Products were among the most popular heartburn drugs, used by thousands of people every day. Indeed, Zantac was the first-ever "blockbuster" drug to reach $1 billion in sales.

But recent scientific studies confirmed what Defendants knew or should have known decades ago: ranitidine transforms over time and under natural conditions into high levels of N-Nitrosodimethylamine ("NDMA"), a carcinogen that is potent and dangerous. The U.S. Food and Drug Administration ("FDA") recognizes NDMA as "a probable human carcinogen"[1] and the

[1] https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market.

World Health Organization has described it as "clearly carcinogenic."[2] Its only use is to induce cancerous tumors in animals as part of laboratory research and experiments; it has no medicinal purpose.

In 2019, an analytical pharmacy ran tests on Zantac and discovered the link between ranitidine and NDMA and that ranitidine itself is unstable and can break down into NDMA, particularly in the environment of the stomach. On September 13, 2019, the analytical pharmacy filed a citizen petition asking the FDA to recall all products that contain ranitidine. In early October 2019, the FDA ordered testing on Zantac and other Ranitidine-Containing Products and specified the protocols for such testing. Within days of the FDA's announcement, certain Defendants recalled Zantac and Ranitidine-Containing Products in the United States and internationally. On November 1, 2019, the FDA announced that its recent testing showed "unacceptable levels" of NDMA in Zantac and other Ranitidine-Containing Products and requested that all manufacturers recall Zantac and other Ranitidine-Containing Products. Ultimately, on April 1, 2020, the FDA called for a withdrawal of Zantac and all other Ranitidine-Containing Products in the United States, citing unacceptable levels of NDMA in those drugs.

While any exposure to NDMA can be harmful, the FDA has set an allowable daily limit of 96 nanograms (ng) of NDMA. Tests of ranitidine revealed NDMA levels as high as ***304,500 ng*** per tablet, which is ***3,171 times*** the maximum daily limit. For reference, "the typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg

[2] R.G. Liteplo et al., Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine, World Health Organization (2002), https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

once nightly for four to eight weeks, and maintenance doses of 150 mg once daily."[3] Thus, individuals who ingested Zantac and other Ranitidine-Containing Products have been exposed to staggering levels of carcinogenic NDMA.

As these recent revelations make clear, people who ingested Zantac and/or other Ranitidine-Containing Products, including Plaintiffs and the Classes face a significantly increased risk of developing serious and potentially fatal cancers. Those cancers include serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers (the "Subject Cancers").

Medical monitoring is a recognized cause of action or form of relief (depending on state law) that allows a plaintiff and class members to obtain diagnostic medical examinations that are funded and/or reimbursed by a defendant, when the defendant's tortious conduct has exposed the plaintiff and class members to an increased risk of harm that proximately causes the need for the comprehensive diagnostic examinations.

In other words, medical monitoring recognizes that plaintiffs and class members can be significantly harmed, notwithstanding the latent exposure of that harm. To obtain relief, plaintiffs generally must prove exposure to a hazardous substance at greater than background levels, caused by the defendant's tortious conduct, which significantly increases the risk of contracting a serious latent disease.[4] The proposed monitoring procedure must permit early detection, be reasonably necessary, and differ from routine medical treatment.[5]

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[3] *LiverTox: Clinical and Research Information on Drug-Induced Liver Injury [Internet], Ranitidine*, Nat'l Inst. Diabetes & Digestive & Kidney Diseases (Updated Jan. 25, 2018), https://www.ncbi.nlm.nih.gov/books/NBK548867/.

[4] *See, e.g., Petito v. A.H. Robins Co., Inc.*, 750 So. 2d 103, 106-07 (Fla. Dist. Ct. App. 1999).

[5] *Id.*

Some states do not require a present physical injury as a condition to obtaining medical monitoring relief; rather, the injury is the exposure to the toxic materials and concomitant increased risk of harm, and/or the expensive diagnostic examinations plaintiff will incur as a result of that increased risk. Other states require a plaintiff to plead a physical manifestation (or present physical injury) of some sort, along with a significantly increased risk of harm.

Plaintiffs and the Classes seek medical monitoring in those 14 states where present physical injury is *not* required, and where a significantly increased risk of harm (and/or related diagnostic examination costs) is a legally sufficient injury.

Here, Defendants *inter alia* designed, manufactured, distributed, packaged, labeled, marketed, and/or sold Zantac and other Ranitidine-Containing Products without proper expiration dates and appropriate packaging; failed to ensure the proper conditions for the manufacture, transportation, handling, and storage of Zantac and other Ranitidine-Containing Products; and failed to disclose material facts regarding the safety of Zantac and other Ranitidine-Containing Products and the dangers and risks associated with their intended use. In doing so, Defendants breached their respective duties to Plaintiffs and the Classes.

Plaintiffs and the Classes ingested Zantac and/or other Ranitidine-Containing Products that contained excessive and unacceptable levels of NDMA, a potent carcinogen. As a result, Plaintiffs and the Classes were exposed to a hazardous substance at greater than background levels and sustained a significantly increased risk of developing the Subject Cancers. Based on their increased risk, Plaintiffs and the Classes need medical monitoring that is different than routine medical treatment to permit early detection of the Subject Cancers, as well as treatments and/or medications.

This Medical Monitoring Complaint is drafted and organized based on the Court's recent

Orders. As detailed below, Plaintiffs, individually and on behalf of the Classes (comprised of individuals who ingested Defendants' Zantac and/or other Ranitidine-Containing Products in specific identified States), seek medical monitoring as a result of their exposure to Defendants' Zantac and/or other Ranitidine-Containing Products under the law of the State in which each Plaintiff resided at the time of use.

Plaintiffs bring separate claims against five categories of Defendants. Plaintiffs' claims are organized first by Defendant group, then by Defendant, and finally by the State in which each respective Plaintiff used the applicable Zantac and/or other Ranitidine-Containing Products as follows:

(a) Brand Prescription Manufacturer Defendant GSK, which manufactured, distributed, and sold prescription Brand Zantac;

(b) Brand OTC Manufacturer Defendants GSK, BI, Pfizer, and Sanofi, which manufactured, distributed, and sold OTC Brand Zantac;

(c) Generic Prescription Manufacturer Defendants Amneal, Dr. Reddy's, Sandoz, Strides, and Teva, which manufactured, distributed, and sold Ranitidine-Containing Products as generic prescription medications;

(d) Store-Brand Defendants CVS, Rite Aid, Walgreens, and Walmart, which are private-label distributors that contracted with one or more Store-Brand Manufacturer Defendants to manufacture Ranitidine-Containing Products sold under their respective store-brand names; and

(e) Store-Brand Manufacturer Defendants Apotex, Dr. Reddy's, Perrigo, and Strides, each of which contracted with one or more Store-Brand Defendants to manufacture store-brand Ranitidine-Containing Products.

II. JURISDICTION AND VENUE

1. This Court has original subject-matter jurisdiction over this action under 28 U.S.C. §1331 (federal question) and 18 U.S.C. §1964 (civil remedies). This Court also has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005, 28 U.S.C. §1332(d)(2), because: (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interest and costs; and (c) at least one Plaintiff is a citizen of a different state than at least one Defendant. In addition, this Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. §1367.

2. This Court has personal jurisdiction over Defendants under Fla. Stat. Ann. §48.193 and 18 U.S.C. §1965(b) and (d). This Court also has pendent personal jurisdiction over Defendants.

3. In addition and/or in the alternative, Defendants and/or their agents or alter egos each have significant contacts with each of the States and territories of the United States because they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products within each of the States and territories of the United States, and/or they derived revenue from the sale of their Ranitidine-Containing Products in each of the States and territories of the United States, through the purposeful direction of their activities to the States and territories of the United States and purposeful availment of the protections of the laws of the States and territories of the United States, such that personal jurisdiction would be proper in those States and territories under traditional notions of fair play and substantial justice.

4. In addition and/or in the alternative, the district to which each Plaintiff's action may be remanded upon conclusion of these pretrial proceedings pursuant to 28 U.S.C. §1407(a) will have personal jurisdiction over the Defendants who themselves or through an agent or alter ego

are incorporated within that district, have a principal place of business in that district, or conduct a substantial amount of business in that district, such that they are essentially at home in that district and, thus, that personal jurisdiction would be proper in that district under traditional notions of fair play and substantial justice.

5. Venue is proper in this District under 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, and otherwise conducted extensive business, within this District. In addition and/or in the alternative, venue is proper under 28 U.S.C. §1407(a) and the Conditional Transfer Orders of the Judicial Panel on Multidistrict Litigation.

III. PARTIES

A. DEFENDANTS

6. Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold Zantac or generic Ranitidine-Containing Products.

1. Brand Manufacturer Defendants (Prescription and OTC)

GlaxoSmithKline (GSK)

7. Defendant GlaxoSmithKline LLC is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania 19112. Defendant GlaxoSmithKline LLC's sole member is Defendant GlaxoSmithKline (America) Inc., a Delaware corporation with its principal place of business in that state. Defendant GlaxoSmithKline LLC is a citizen of Delaware.

8. Defendant GlaxoSmithKline (America) Inc. is a Delaware corporation with its principal place of business located at 1105 North Market Street, Suite 622, Wilmington, Delaware

19801. Defendant GlaxoSmithKline (America) Inc. is a citizen of Delaware.

9. Defendant GlaxoSmithKline plc is a public limited company formed and existing under the laws of the United Kingdom, having a principal place of business at 980 Great West Road, Brentford Middlesex XO, TW8 9GS, United Kingdom. Defendant GlaxoSmithKline plc is a citizen of the United Kingdom.

10. Defendants GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are subsidiaries of Defendant GlaxoSmithKline plc.[6] Collectively, all of these entities shall be referred to as "GSK." Defendant GSK is a manufacturer, distributor, and seller of brand prescription and OTC Zantac.

Pfizer

11. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Defendant Pfizer is a citizen of Delaware and New York. Defendant Pfizer is a manufacturer, distributor, and seller of brand OTC Zantac.

Boehringer Ingelheim (BI)[7]

12. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a citizen of Delaware and Connecticut.

13. Defendant Boehringer Ingelheim Corporation is a Nevada corporation with its

[6] Pursuant to the Joint Stipulation Relating to GlaxoSmithKline PLC [DE 1470], Defendant GlaxoSmithKline LLC stipulated that Defendants GlaxoSmithKline plc is an affiliated company, and that Defendant GlaxoSmithKline LLC is the proper party for purposes of all claims asserted against Defendant GlaxoSmithKline plc in this litigation.

[7] Defendant Boehringer Ingelheim also manufactured generic ranitidine under ANDA 074662, as well as through its former subsidiary Ben Venue Laboratories Inc. d/b/a Bedford Laboratories (ANDA 074764). Ben Venue Laboratories Inc. is no longer in operation.

principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Corporation is a citizen of Nevada and Connecticut.

14. Defendant Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim USA Corporation is a citizen of Delaware and Connecticut.

15. Defendant Boehringer Ingelheim International GmbH is a limited liability company formed and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim AM Rhein, Rheinland-Phalz, Germany. Defendant Boehringer Ingelheim International GmbH is a citizen of Germany.

16. Defendant Boehringer Ingelheim Promeco, S.A. de C.V. is a foreign corporation organized and existing under the laws of Mexico with its principal place of business located at Maiz No. 49, Barrio Xaltocan, Xochimilco, Ciudad de Mexico, 16090 Mexico. Defendant Boehringer Ingelheim Promeco, S.A. de C.V. is a citizen of Mexico.

17. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a direct or indirect subsidiary of Defendants Boehringer Ingelheim Corporation and Boehringer Ingelheim USA Corporation, which are themselves wholly owned, directly or indirectly, by Defendant Boehringer Ingelheim International GmbH.8 Collectively, all of these entities and Defendant Boehringer Ingelheim Promeco, S.A. de C.V. shall be referred to as "Boehringer Ingelheim" or "BI." Defendant BI is a manufacturer, distributor, and seller of brand OTC Zantac.

[8] Pursuant to the Joint Stipulation Relating to Boehringer Ingelheim Defendants [DE 1478], Defendants Boehringer Ingelheim Pharmaceuticals, Inc. stipulated that Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Promeco, S.A. de C.V. are affiliated companies, and that Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is the proper party for purposes of all claims asserted against Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Promeco, S.A. de C.V. in this litigation.

Sanofi

18. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. LLC's sole member is Defendant Sanofi U.S. Services, Inc., a Delaware corporation with its principal place of business in New Jersey. Defendant Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

19. Defendant Sanofi US Services Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi US Services Inc. is a citizen of Delaware and New Jersey.

20. Defendant Sanofi SA is a corporation formed and existing under the laws of France, having a principal place of business at 54 Rue La Boetie, 8th Arrondissement, Paris, France 75008. Defendant Sanofi SA is a citizen of France.

21. Defendant Patheon Manufacturing Services LLC is a Delaware limited liability company with its principal place of business located at 5900 Martin Luther King Jr. Highway, Greenville, North Carolina 27834. Thermo Fisher Scientific, Inc. is the sole member of Defendant Patheon Manufacturing Services LLC. Thermo Fisher Scientific, Inc. is a Delaware corporation with its principal place of business in Massachusetts. Defendant Patheon Manufacturing Services LLC is a citizen of Delaware and Massachusetts.

22. Defendant Chattem, Inc. is a Tennessee corporation with its principal place of business located at 1715 West 38th Street Chattanooga, Tennessee 37409. Defendant Chattem, Inc. is a citizen of Tennessee. Defendant Chattem, Inc purchased ranitidine and repackaged and/or relabeled it under its own brand.

23. Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., and Chattem,

Inc. are subsidiaries of Defendant Sanofi SA.[9] Defendants Patheon Manufacturing Services LLC and Boehringer Ingelheim Promeco, S.A. de C.V. packaged and manufactured the finished Zantac product for Sanofi. Collectively, all of these entities shall be referred to as "Sanofi." Defendant Sanofi is a manufacturer, distributor, and seller of brand OTC Zantac.

24. Defendants BI, GSK, Pfizer, and Sanofi, shall be referred to collectively as the "Brand Manufacturer Defendants." At all relevant times, the Brand Manufacturer Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Zantac within each of the States and Territories of the United States, Puerto Rico, and the District of Columbia.[10]

2. Generic Prescription Manufacturer Defendants and/or Store-Brand Manufacturer Defendants

Amneal

25. Defendant Amneal Pharmaceuticals LLC is a Delaware limited liability company with its principal place of business located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807. The sole member of Defendant Amneal Pharmaceuticals LLC is non-party Amneal Pharmaceuticals, Inc., a Delaware corporation with its principal place of business in New Jersey. Amneal Pharmaceuticals LLC is a citizen of Delaware and New Jersey.

26. Defendant Amneal Pharmaceuticals LLC registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.[11]

[9] Pursuant to the Joint Stipulation Relating to Sanofi Defendants [DE 1450], Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. stipulated that Defendant Sanofi SA is an affiliated company, and that Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are the proper parties for purposes of all claims asserted against Sanofi SA relief sought in this litigation.

[10] All references to "States" include Puerto Rico and the District of Columbia.

[11] Amneal_prod1_0000001129.

27. Defendant Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company with its principal place of business located at 50 Horseblock Road, Brookhaven, New York 11719.

28. The membership interest of Defendant Amneal Pharmaceuticals of New York, LLC is owned by non-party Amneal Pharmaceuticals, Inc., a Delaware corporation with its principal place of business located in New Jersey, through an intervening limited liability company. Defendant Amneal Pharmaceuticals of New York, LLC is a citizen of Delaware and New Jersey.

29. Defendant Amneal Pharmaceuticals of New York, LLC applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Defendant Amneal Pharmaceuticals of New York, LLC applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States. Defendant Amneal Pharmaceuticals of New York, LLC registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.[12]

30. Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC are subsidiaries of non-party Amneal Pharmaceuticals, Inc. Collectively, these entities shall be referred to as "Amneal."

31. Defendant Amneal is a manufacturer, distributor, and seller of generic prescription Ranitidine-Containing Products.

Apotex

32. Defendant Apotex Corporation is a Delaware corporation with its principal place

[12] Amneal_prod1_0000001129.

of business located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Defendant Apotex Corporation is a citizen of Delaware and Florida.

33. Defendant Apotex Corporation applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States. Further, Defendant Apotex Corporation is Defendant Apotex Inc.'s appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including Ranitidine-Containing Products. Defendant Apotex Corporation as a regulatory agent also fulfills a regulatory compliance role for Defendant Apotex Inc. by regularly filing materials the FDA requires abbreviated new drug application ("ANDA") holders to provide to maintain their right to manufacture drugs.[13]

34. Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada with its principal place of business located at 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada. Defendant Apotex Inc. is a citizen of Canada.

35. Defendant Apotex Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Further, Defendant Apotex Inc. registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.[14]

36. Defendant Apotex Corporation is a subsidiary of Defendant Apotex Inc. Collectively, these entities shall be referred to as "Apotex."

37. Defendant Apotex is a contract manufacturer that contracted with one or more Store-Brand Defendants to manufacture store-brand Ranitidine-Containing Products.

[13] Apotex Corp 00255.
[14] Apotex Corp 00121.

Dr. Reddy's

38. Defendant Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business located at 107 College Road East, Princeton, New Jersey 08540. Defendant Dr. Reddy's Laboratories, Inc. is a citizen of New Jersey.

39. Defendant Dr. Reddy's Laboratories, Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Defendant Dr. Reddy's Laboratories, Inc. also applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States.

40. Defendant Dr. Reddy's Laboratories, Inc. is also the appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including Ranitidine-Containing Products manufactured by Defendant Dr. Reddy's Laboratories, Ltd.

41. Defendant Dr. Reddy's Laboratories, Inc. as a regulatory agent also fulfills a regulatory compliance role for other Dr. Reddy's entities by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.[15]

42. Defendant Dr. Reddy's Laboratories, Ltd.[16] is corporation organized and existing under the laws of India with its principal place of business located at 8-2-337, Road No. 3, Banjara Hills, Hyderabad Telangana 500 034, India. Defendant Dr. Reddy's Laboratories, Ltd. is a citizen of India.

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[15] DRLMDL 004629.

[16] Pursuant to the Joint Stipulation Relating to Dr. Reddy's Defendants [DE 2029], Dr. Reddy's Laboratories, Inc., stipulated that Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories SA are affiliated companies, and that Defendant Dr. Reddy's Laboratories, Inc. is the proper party for purposes of all claims asserted against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories SA in this litigation.

43. Defendant Dr. Reddy's Laboratories, Ltd. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Defendant Dr. Reddy's Laboratories, Ltd. also applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States. Defendant Dr. Reddy's Laboratories, Ltd. further registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

44. Defendant Dr. Reddy's Laboratories LLC is a limited liability company with its principal place of business located at 107 College Road East, Princeton, New Jersey 08540. The LLC has three registered officers, each of whom are citizens of New Jersey. Dr. Reddy's Laboratories LLC is a citizen of New Jersey.

45. Defendant Dr. Reddy's Laboratories LLC registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.[17]

46. Defendant Dr. Reddy's Laboratories SA is a corporation organized and existing under the laws of Switzerland with its principal place of business located at Elisabethenanlage, 11, Basel, 4051 Switzerland. Defendant Dr. Reddy's Laboratories SA is a citizen of Switzerland.

47. Defendant Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories LLC are subsidiaries of Dr. Reddy's Laboratories SA. Collectively, these entities shall be referred to as "Dr. Reddy's."

48. Defendant Dr. Reddy's is a manufacturer, distributor, and seller of generic prescription Ranitidine-Containing Products and is also a contract manufacturer that contracted

[17] DRLMDL 004629.

with one or more Store-Brand Defendants to manufacture store-brand Ranitidine-Containing Products.

Glenmark

49. Defendant Glenmark Pharmaceuticals, Inc., USA (f/k/a Glenmark Generics, Inc. USA) is a Delaware corporation with its principal place of business located at 750 Corporate Drive, Mahwah, New Jersey 07430. Defendant Glenmark Pharmaceuticals, Inc., USA is a citizen of Delaware and New Jersey.

50. Defendant Glenmark Pharmaceuticals, Inc., USA applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Defendant Glenmark Pharmaceuticals, Inc., USA also applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States.

51. Defendant Glenmark Pharmaceuticals, Inc., USA is also Defendant Glenmark Pharmaceuticals Ltd.'s appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including Ranitidine-Containing Products. Defendant Glenmark Pharmaceuticals, Inc., USA as a regulatory agent also fulfills a regulatory compliance role for Glenmark Pharmaceuticals Ltd. by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.[18]

52. Defendant Glenmark Pharmaceuticals Ltd. (f/k/a Glenmark Generics Ltd.) is a corporation organized and existing under the laws of India with its principal place of business located at Glenmark House, B.D. Sawant Marg., Chakala, Western Express Highway, Andheri

[18] Glenmark 002130, 0030383, 0003691.

(E), Mumbai 400 099, India. Defendant Glenmark Pharmaceuticals Ltd. is a citizen of India.

53. Defendant Glenmark Pharmaceuticals Ltd. registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

54. Defendant Glenmark Pharmaceuticals, Inc., USA is a subsidiary of Defendant Glenmark Pharmaceuticals Ltd. Collectively, these entities shall be referred to as "Glenmark."

55. Defendant Glenmark is a manufacturer, distributor, and seller of generic prescription Ranitidine-Containing Products.

Perrigo

56. Defendant L. Perrigo Co. is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. Defendant L. Perrigo Co. is a citizen of Michigan.

57. Defendant L. Perrigo Co. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Defendant L. Perrigo Co. also applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States. Defendant L. Perrigo Co. further registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

58. Defendant Perrigo Company is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. Defendant Perrigo Company is a citizen of Michigan.

59. Defendant Perrigo Research & Development Company is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. Defendant Perrigo Research & Development Company is a citizen of Michigan.

60. Defendant Perrigo Research & Development Company applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

61. L. Perrigo Co., Perrigo Company, and Perrigo Research & Development Company are subsidiaries of non-party Perrigo Company, plc., a corporation organized and existing under the laws of Ireland with its principal place of business in Ireland. Collectively, these entities shall be referred to as "Perrigo."[19]

62. Defendant Perrigo is a contract manufacturer that contracted with one or more Store-Brand Defendants to manufacture store-brand Ranitidine-Containing Products.

Sandoz

63. Defendant Sandoz Inc. ("Sandoz") is a Colorado corporation with its principal place of business located at 100 College Road West, Princeton, New Jersey 08540. Defendant Sandoz is a citizen of Colorado and New Jersey.

64. Defendant Sandoz applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Defendant Sandoz applied to the FDA for the power and privilege of listing and labeling Ranitidine-Containing Products for sale in all states and territories within the United States.

65. Defendant Sandoz is a manufacturer, distributor, and seller of generic prescription Ranitidine-Containing Products.

[19] Pursuant to the Joint Stipulation Relating to Perrigo Defendants [DE 1555], L. Perrigo Co., Perrigo Company, and Perrigo Research & Development Company stipulated that they are the proper parties for purposes of all relief sought in this litigation.

Strides

66. Defendant Strides Pharma, Inc. ("Strides") is a New Jersey corporation with its principal place of business located at 2 Tower Center, Boulevard Suite 1102, East Brunswick, New Jersey 08816. Defendant Strides is a citizen of New Jersey.

67. Strides is a subsidiary of non-parties Strides Pharma Science Ltd., a corporation organized and existing under the laws of India, and Strides Global Pte Ltd, a corporation organized and existing under the laws of Singapore.

68. Defendant Strides registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.[20]

69. Defendant Strides is a manufacturer, distributor, and seller of generic prescription Ranitidine-Containing Products and is also a contract manufacturer that contracted with one or more Store-Brand Defendants to manufacture store-brand Ranitidine-Containing Products.21

Teva

70. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business located at 1877 Kawai Road, Lincolnton, North Carolina 28092. The membership interest of Defendant Actavis Mid Atlantic LLC is owned by Teva Pharmaceuticals U.S.A., Inc., a Delaware corporation with its principal place of business in Pennsylvania, either directly or through an intervening limited liability company. Defendant Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business in

[20] SPIRND00011271.

[21] Pursuant to the Joint Stipulation Relating to Strides Defendants [DE 1635], Defendant Strides stipulated that non-parties Strides Pharma Science Ltd. and Strides Global Pte Ltd. are affiliated companies, and that Defendant Strides is the proper party in interest for purposes of all claims asserted in this litigation. As alleged below, multiple Strides entities held ANDAs and manufactured generic ranitidine.

Pennsylvania. Actavis Mid Atlantic LLC is a citizen of Delaware and Pennsylvania.

71. Defendant Actavis Mid Atlantic LLC applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

72. Defendant Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals U.S.A., Inc. is a citizen of Delaware and Pennsylvania.

73. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business located at 400 Interpace Parkway, Building A., Parsippany, New Jersey 07054. Watson Laboratories, Inc. is a citizen of Nevada and New Jersey.

74. Defendant Watson Laboratories, Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

75. In 2006, non-party Teva Pharmaceutical Industries Ltd. acquired IVAX Pharmaceuticals. IVAX LLC and IVAX Pharmaceuticals, Inc. are subsidiaries of Teva Pharmaceutical U.S.A., Inc. (collectively, "IVAX"). IVAX applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval, which rights were subsequently transferred to Teva.

76. Defendants Actavis Mid Atlantic LLC, Teva Pharmaceuticals U.S.A., Inc., and Watson Laboratories, Inc. are subsidiaries of non-party Teva Pharmaceutical Industries Ltd., a corporation organized and existing under the laws of Israel with its principal place of business located in Israel. Collectively, all of these entities shall be referred to as "Teva." Defendant Teva is a manufacturer, distributor, and seller of generic prescription Ranitidine-Containing Products.

77. Defendants Amneal, Apotex, Dr. Reddy's, Glenmark, Perrigo, Sandoz, Strides, and Teva are collectively referred to as "Generic Manufacturers." At all relevant times, the Generic Manufacturers have conducted business and derived substantial revenue from their manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Ranitidine-Containing Products within each of the States and Territories of the United States. GSK, Pfizer, BI, Sanofi, Amneal, Apotex, Dr. Reddy's, Glenmark, Perrigo, Sandoz, Strides, and Teva may be collectively referred to as "Manufacturer Defendants."

3. Store-Brand Defendants

CVS

78. Defendant CVS Pharmacy, Inc. ("CVS") is a Delaware corporation with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895. Defendant CVS is a citizen of Delaware and Rhode Island.

79. Defendant CVS is a private-label distributor that contracts with one or more contract manufacturer to manufacture Ranitidine-Containing Products sold by CVS under its store-brand, CVS Health.

Rite Aid

80. Defendant Rite Aid Corporation ("Rite Aid") is a Delaware corporation with its principal place of business located at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid is a citizen of Delaware and Pennsylvania.

81. Defendant Rite Aid is a private-label distributor that contracts with one or more contract manufacturer to manufacture Ranitidine-Containing Products sold by Rite Aid under its store-brand, Rite Aid.

Walgreens

82. Defendant Walgreen Co. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreen Co. is a citizen of Delaware and Illinois.

83. Defendant Duane Reade, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Duane Reade, Inc. is a citizen of Delaware and Illinois.

84. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreens Boots Alliance, Inc. is a citizen of Delaware and Illinois.

85. Defendant Walgreens Boots Alliance, Inc. purchased ranitidine and repackaged and/or relabeled it under Defendant's own brand.

86. Walgreen Co. and Duane Reade, Inc. are subsidiaries of Walgreens Boots Alliance, Inc. Collectively, these entities shall be referred to as "Walgreens."

87. Defendant Walgreens is a private-label distributor that contracts with one or more contract manufacturer to manufacture Ranitidine-Containing Products sold by Walgreens under its store-brand, Wal-Zan.

Walmart

88. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business located at 702 SW 8th Street, Bentonville, Arkansas 72716. Walmart Inc. is a citizen of Delaware and Arkansas.

89. Defendant Sam's West, Inc. is an Arkansas corporation with its principal place of business located at 702 SW 8th Street, Bentonville, Arkansas 72716. Sam's West, Inc. is a citizen of Arkansas.

90. Sam's West, Inc. is a subsidiary of Walmart Inc. Collectively, these entities shall be referred to as "Walmart."

91. Defendant Walmart is a private-label distributor that contracts with one or more contract manufacturer to manufacture Ranitidine-Containing Products sold by Walmart under its store-brand, Equate.

B. PLAINTIFFS

92. Plaintiffs are individuals who purchased and used Defendants' Ranitidine-Containing Products, as described below and *infra*, Section VI.

93. Plaintiff Elaine Aaron (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products in Missouri from approximately 2009 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2009 to 2020 (manufactured by Sandoz and Glenmark). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Strides, and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers[22] and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a

[22] As set out above, the Subject Cancers include serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers ("Subject Cancers").

significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

94. Plaintiff Ida Adams (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2000 to 2005 and 2012 in West Virginia as a citizen of West Virginia, and from approximately 2005 to 2017 in Maryland as a citizen of Maryland. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: (a) OTC 150 mg Zantac tablets and capsules from approximately 2005 to 2017 in Maryland while a citizen of Maryland (manufactured by Pfizer, BI and Sanofi); and (b) OTC 150 mg Zantac tablets and capsules from approximately 2000 to 2005 and 2012 in West Virginia while a citizen of West Virginia (manufactured by Pfizer and BI). Thus, Pfizer, BI and Sanofi are "Defendants" with respect to purchases made in Maryland while a citizen of Maryland, unless otherwise specified; and Pfizer and BI are "Defendants" with respect to purchases made in West Virginia while a citizen of West Virginia, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

95. Plaintiff Virginia Aragon (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products in California from

approximately 2006 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC Zantac tablets and capsules from approximately 2006 to 2020 (manufactured by Pfizer, BI, and Sanofi); and (b) prescription 300 mg generic ranitidine tablets and capsules from approximately 2006 to 2020 (manufactured by Amneal). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 300 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, Pfizer, BI, Sanofi, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

96. Plaintiff Irma Arcaya (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2014 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2014 to 2020. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the

purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

97. Plaintiff Golbenaz Bakhtiar (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products in California from approximately 2000 to December 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC Zantac tablets and capsules from approximately 2000 to 2019 (manufactured by Pfizer, BI, and Sanofi); (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2005 to 2019; and (c) prescription Zantac tablets and capsules beginning in approximately 2000 (manufactured by GSK). Plaintiff also purchased and used OTC 150 mg Walgreens-branded and Rite Aid-branded ranitidine tablets and capsules from Walgreens and Rite Aid, respectively, from approximately 2005 to 2019, but based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's, Perrigo, Strides, and Apotex manufactured OTC 150 mg Walgreens-branded ranitidine tablets and capsules for Walgreens, and Perrigo, Strides, and Apotex manufactured OTC 150 mg Rite Aid-branded ranitidine tablets and capsules for Rite Aid, and therefore, Dr. Reddy's, Perrigo, Strides, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded

ranitidine tablets and capsules purchased by Plaintiff. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, Walgreens, Rite Aid, GSK, Pfizer, BI, Sanofi, Dr. Reddy's, Perrigo, Apotex, Amneal, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

98. Plaintiff Felicia Ball (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products in Pennsylvania from approximately 2000 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) prescription Zantac (manufactured by GSK); and (b) prescription 150 mg and 300 generic ranitidine tablets and capsules from approximately 2000 to 2020 (manufactured by Strides and Amneal). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Glenmark, Sandoz, and Teva; and prescription 300 mg generic tablets and capsules by one or more of the following defendants: Dr. Reddy's, Glenmark, and Teva. Thus, GSK, Amneal, Dr. Reddy's, Glenmark, Strides, Sandoz, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise

specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

99. Plaintiff Jeannie Black (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2015 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC Zantac tablets and capsules from approximately 2015 to 2018 (manufactured by BI and Sanofi); and (b) prescription 300 mg generic ranitidine tablets and capsules from approximately 2018 to 2020 (manufactured by Glenmark and Strides). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 300 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, and Sandoz. Thus, BI, Sanofi, Glenmark, Strides, Dr. Reddy's, and Sandoz are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants'

wrongful conduct.

100. Plaintiff Antrenise Campbell (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products in Missouri from approximately 1998 to 2013. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) prescription 150 mg generic ranitidine tablets and capsules from approximately 1998 to 2008; and (b) OTC 150 mg Zantac tablets and capsules from approximately 2008 to 2013 (manufactured by BI). Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Sandoz, and Teva. Thus, BI, Dr. Reddy's, Sandoz, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

101. Plaintiff Sonia Diaz (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2017 to 2020 while a resident of Florida. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included: (a) prescription 150 mg and 300 mg generic ranitidine tablets and capsules from approximately 2017 to 2020 in Florida (manufactured by Amneal); and (b) OTC Zantac tablets and capsules from approximately 2017 to 2020 in Florida

(manufactured by Sanofi). Further, based on the limited discovery obtained to date, Plaintiff also purchased and used additional prescription 150 mg and 300 mg generic ranitidine tablets and capsules from approximately 2017 to 2020 manufactured by Dr. Reddy's, Glenmark, Sandoz, and Strides in Florida while a citizen of Florida. Thus, Dr. Reddy's, Glenmark, Sandoz, Strides, Sanofi and Amneal are "Defendants" for the purposes of Plaintiff's claims for purchases in Florida while a citizen of Florida, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

102. Plaintiff Teresa Dowler (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2011 to December 2019 in Indiana. The Ranitidine-Containing Products Plaintiff purchased and used specifically included (a) OTC 150 mg Zantac tablets and capsules from approximately 2012 to 2019 (manufactured by BI and Sanofi); (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2017 to December 2019 (manufactured by Strides): (c) and prescription 150 mg Zantac tablets and capsules from approximately 2011 to 2013 (manufactured by GSK). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, and Sandoz. Thus, BI, Sanofi, Strides, GSK, Amneal, Dr. Reddy's, Glenmark, and Sandoz are "Defendants" for the purposes of

Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

103. Plaintiff Jonathan Ferguson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products in Nevada from approximately 1996 to 1999 while a citizen of Nevada, and in California from approximately 2007 to 2012 while a citizen of California. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC Zantac tablets and capsules from approximately 1996 to 1999 in Nevada while a citizen of Nevada (manufactured by GSK and Pfizer); (b) OTC Zantac tablets and capsules from approximately 2007 to 2012 while a citizen of California (manufactured by BI); and (c) OTC Walmart-branded ranitidine tablets from Walmart, and Walgreens-branded ranitidine tablets from Walgreens from approximately from 2010 to 2012 in California while a citizen of California. Based on the limited available sources of information and discovery conducted to date, Plaintiff does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's and Perrigo manufactured OTC tablets and capsules for Walmart, and Dr. Reddy's and Perrigo manufactured OTC tablets and capsules for Walgreens, and therefore, Dr. Reddy's and Perrigo are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, GSK

and Pfizer are "Defendants" with respect to purchases made in Nevada while a citizen of Nevada, unless otherwise specified; and BI, Walmart, Walgreens, Dr. Reddy's, and Perrigo are "Defendants" with respect to purchases made in California while a citizen of California, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

104. Plaintiff Michael Fesser (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2010 to December 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2010 to 2019 (manufactured by Amneal). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly

increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

105. Plaintiff Karen Foster (for the purpose of this paragraph, "Plaintiff"), is a citizen of Virginia. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2013 to 2017 while a citizen of Florida. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: (a) prescription 150 mg generic ranitidine tablets and capsules from approximately 2013 to 2017 in Florida while a citizen of Florida (manufactured by Glenmark); and (b) OTC 150 mg Zantac tablets and capsules in or around 2013 in Florida while a citizen of Florida (manufactured by BI). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, Strides, and Teva. Thus, BI, Amneal, Glenmark, Sandoz, Dr. Reddy's, Strides, and Teva are "Defendants" with respect to purchases made in Florida while a citizen of Florida, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

106. Plaintiff Michael Galloway (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products in Florida from

approximately 1997 through 1999 while a resident of Florida, and in Ohio from approximately 1999 through October 2019 while a resident of Ohio. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) prescription 150 mg Zantac tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida (manufactured by GSK); (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida; (c) OTC Zantac tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida (manufactured by GSK and Pfizer); (d) prescription 150 mg Zantac tablets and capsules beginning in approximately 1999 in Ohio while a citizen of Ohio (manufactured by GSK); (e) prescription 150 mg generic ranitidine tablets and capsules from approximately 1999 through October 2019 in Ohio while a citizen of Ohio (manufactured by Teva); and (f) OTC Zantac tablets and capsules from approximately 1999 through October 2019 in Ohio while a citizen of Ohio (manufactured by Pfizer, BI, and Sanofi). Further, based on the limited discovery obtained to date, Plaintiff purchased additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, GSK, Pfizer, Sandoz, and Teva are "Defendants" with respect to purchases made in Florida while a citizen of Florida unless otherwise specified; and GSK, Pfizer, BI, Sanofi, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" with respect to purchases made in Ohio while a citizen of Ohio unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing

the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

107. Plaintiff Cynthia Gibbs (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products in Missouri from approximately 2005 to 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg and 300 mg generic ranitidine tablets and capsules from approximately 2005 to 2019. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

108. Plaintiff Timberly Goble (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2013 to 2019 while a citizen of Indiana. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: prescription 150 mg generic ranitidine tablets and capsules from approximately 2013 to 2019 in Indiana while a citizen of Indiana (manufactured by Strides and Glenmark). Further, based on the limited discovery obtained to date, Plaintiff

purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, and Teva. Thus, Glenmark, Amneal, Dr. Reddy's, Sandoz, Strides, and Teva are "Defendants" for purchases made in Indiana while a citizen of Indiana, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

109. Plaintiff Alberta Griffin (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products in Maryland from approximately 2000 to March 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included: (a) prescription Zantac tablets and capsules beginning in approximately 2000 (manufactured by GSK); (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2013 to March 2020 (manufactured by Strides and Glenmark); and (c) OTC 150 mg Zantac tablets and capsules from approximately 2000 to March 2020 (manufactured by Pfizer, BI, and Sanofi). Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, and Teva. Thus, GSK, Strides, Glenmark, Pfizer, BI, Sanofi, Amneal, Dr. Reddy's, Sandoz, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and

proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

110. Plaintiff Joyce Guerrieri (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products in Pennsylvania from approximately 2000 to September 2019 while a citizen of Pennsylvania. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules. Based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

111. Plaintiff Royal Handy (for the purpose of this paragraph, "Plaintiff"), is a citizen of

California. Plaintiff purchased and used Ranitidine-Containing Products in California from approximately 2015 to December 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription generic ranitidine tablets and capsules from approximately 2015 to December 2019 manufactured by Glenmark. Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, Teva, and Strides. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Teva, and Strides are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

112. Plaintiff Mynetta Hastings (for the purpose of this paragraph, "Plaintiff"), is a citizen of West Virginia. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2003 to December 2019 as a citizen of West Virginia. The Ranitidine-Containing Products purchased by Plaintiff specifically included the following: (a) prescription generic ranitidine tablets and capsules from approximately 2003 to 2019 (manufactured by Dr. Reddy's, Strides, and Teva); (b) OTC CVS-branded ranitidine tablets and capsules in or about 2019; and (c) OTC Walmart-branded ranitidine tablets and capsules in or about 2019. Plaintiff purchased OTC CVS-branded ranitidine tablets and capsules, and OTC Walmart-branded ranitidine tablets and

capsules, from CVS and Walmart, respectively, in or about 2019, but based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Perrigo, Strides, and Dr. Reddy's manufactured OTC CVS-branded ranitidine tablets and capsules for CVS, and Perrigo, Dr. Reddy's, Strides, and Apotex manufactured OTC Walmart-branded ranitidine tablets and capsules for Walmart, and therefore, Perrigo, Dr. Reddy's, Strides, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Further, based on the limited discovery obtained to date, Plaintiff purchased prescription generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Glenmark, and Sandoz. Thus, Apotex, Walmart, Dr. Reddy's, Strides, Teva, CVS, Perrigo, Amneal, Glenmark, and Sandoz are referred to as "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

113. Plaintiff Patricia Hess (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products in Ohio from approximately 2010 to January 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: (a) prescription 150 mg generic ranitidine tablets and capsules

(manufactured by Dr. Reddy's, Strides, and Sandoz); and (b) OTC Zantac tablets and capsules (manufactured by BI). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Glenmark, and Teva. Plaintiff also purchased and used OTC 75 mg and 150 mg CVS-branded ranitidine tablets and capsules purchased from CVS from approximately 2010 to January 2019 but, based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's, Strides, and Perrigo manufactured OTC 75 mg and 150 mg CVS-branded ranitidine tablets and capsules for CVS, and therefore, Dr. Reddy's, Strides, and Perrigo are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, CVS, BI, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, Teva, and Perrigo are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

114. Plaintiff Hattie Kelley (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2012 to 2018. The Ranitidine-Containing Products purchased and used by Plaintiff

specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately2012 to 2018 (manufactured by Teva and Glenmark). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, and Strides. Thus, Amneal, Dr. Reddy's, Teva, Glenmark, Strides, and Sandoz are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

115. Plaintiff Lorie Kendall-Songer (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2016 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 150 mg Zantac tablets and capsules from approximately 2016 to 2020 (manufactured by BI and Sanofi). Thus, BI and Sanofi are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the

Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

116. Plaintiff Ronda Lockett (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products in Missouri from approximately 1990 to 2000 while a citizen of Missouri. The Ranitidine-Containing Products purchased and used by Plaintiff in Missouri while a citizen of Missouri specifically included (a) prescription Zantac tablets and capsules from approximately 1990 to 1995 (manufactured by GSK); and (b) OTC Zantac tablets and capsules from approximately 1995 to 2000 (manufactured by GSK and Pfizer). Thus, GSK and Pfizer are "Defendants" with respect to purchases made in Missouri while a citizen of Missouri, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

117. Plaintiff Charles Longfield (for the purpose of this paragraph, "Plaintiff"), is a citizen of Nebraska. Plaintiff purchased and used Ranitidine-Containing Products from approximately 1995 to 1996 and 2011 while a citizen of Maryland. The Ranitidine-Containing Products Plaintiff purchased and used while a citizen of Maryland specifically included (a) OTC Zantac tablets and capsules from approximately 1995 to 1996 (manufactured by GSK and Pfizer); and (b) OTC 150 mg Zantac tablets and capsules in or about 2011 (manufactured by BI). Thus, GSK, Pfizer, and BI are "Defendants" for the purposes of Plaintiff's claims, unless otherwise

specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

118. Plaintiff Marva Mccall (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2007 to December 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC Zantac tablets and capsules from approximately 2007 to 2015 (manufactured by BI); and (b) prescription 300 mg generic ranitidine tablets and capsules from approximately 2015 to 2019 (manufactured by Strides and Glenmark). Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 300 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Sandoz, and Teva. Thus, BI, Strides, Glenmark, Dr. Reddy's, Sandoz, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants'

wrongful conduct.

119. Plaintiff Clifton McKinnon (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2008 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC 75 and 150 mg Zantac tablets and capsules from approximately 2008 to 2010 (manufactured by BI); and (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2010 to 2020 (manufactured by Glenmark, Teva, and Strides). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, and Strides. Thus, BI, Glenmark, Strides, Amneal, Dr. Reddy's, Sandoz, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

120. Plaintiff Kristen Monger, as power of attorney and on behalf of, Alexander Monger, (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 1999 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) prescription generic ranitidine syrup from approximately 1999 to 2020 manufactured by Amneal; and (b) prescription

Zantac syrup (manufactured by GSK) from approximately 1999 to 2020. Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription generic ranitidine syrup manufactured by Teva. Thus, Amneal, GSK, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

121. Plaintiff Kristen Monger, as power of attorney and on behalf of, Laura Monger, (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 1997 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included: (a) prescription generic ranitidine syrup from approximately 1997 to 2020; and (b) prescription Zantac syrup (manufactured by GSK). Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription generic ranitidine syrup manufactured by Amneal and Teva. Thus, GSK, Amneal, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of

medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

122. Plaintiff Ricardo Moròn (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 1995 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC Zantac tablets and capsules from approximately 1995 to 2020 manufactured by GSK, Pfizer, BI, and Sanofi. Thus, GSK, Pfizer, BI, and Sanofi are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

123. Plaintiff Kevin Nelson (for the purpose of this paragraph, "Plaintiff"), is a citizen of the District of Columbia. Plaintiff purchased and used Ranitidine-Containing Products in Maryland from approximately May 2018 to December 2018. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules in or around approximately 2018, in Maryland while a citizen of Maryland. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by Amneal, Dr. Reddy's, Glenmark, Sandoz, and Strides. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, and Strides are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of

consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

124. Plaintiff Brenda Newcomb (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products in Missouri from approximately 2016 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2016 to 2020 manufactured by Strides. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, and Teva. Thus, Strides, Amneal, Dr. Reddy's, Glenmark, Sandoz, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

125. Plaintiff Richard Obrien (for the purpose of this paragraph, "Plaintiff"), is a citizen

of California. Plaintiff purchased and used Ranitidine-Containing Products in California from approximately 1998 to November 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC Zantac tablets and capsules from approximately 1998 to 2019 (manufactured by GSK, Pfizer, BI, and Sanofi). Plaintiff also purchased and used OTC 150 mg CVS-branded and Rite Aid-branded ranitidine tablets and capsules purchased from CVS and Rite Aid, respectively, until approximately 2019, but based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's, Strides, and Perrigo manufactured OTC 150 mg CVS-branded ranitidine tablets and capsules for CVS, and Strides, Perrigo and Apotex manufactured 150 mg Rite Aid-branded ranitidine tablets and capsules for Rite Aid, and therefore, Strides, Dr. Reddy's, Perrigo, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, CVS, GSK, Pfizer, BI, Sanofi, Dr. Reddy's, Strides, Perrigo, and Apotex are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

126. Plaintiff Ana Pereira (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from

approximately May 2017 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2017 to 2020 manufactured by Glenmark. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, and Strides. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, and Strides are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

127. Plaintiff Cesar Pinon (for the purpose of this paragraph, "Plaintiff"), is a citizen of Nevada. Plaintiff purchased and used Ranitidine-Containing Products in Nevada from approximately 2009 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 75 mg and 150 mg Zantac tablets and capsules from approximately 2009 to 2015 (manufactured by BI). Thus, BI is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well

as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendant's wrongful conduct.

128. Plaintiff Jeffrey Pisano (for the purpose of this paragraph, "Plaintiff"), is a citizen of Colorado. Plaintiff purchased and used Ranitidine-Containing Products in Colorado from approximately 1998 to February 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC Zantac tablets and capsules from approximately 1998 to 2020 (manufactured by GSK, Pfizer, BI, and Sanofi); (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 1998 to 2003; and (c) prescription 150 mg Zantac tablets and capsules in approximately this same time frame (manufactured by GSK). Plaintiff also purchased and used OTC 150 mg Walmart-branded and Walgreens-branded ranitidine tablets and capsules purchased from Walmart and Walgreens, respectively, until approximately 2020, but based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Perrigo, Dr. Reddy's, Strides, and Apotex manufactured OTC 150 mg Walmart-branded ranitidine tablets and capsules for Walmart, and Walgreens-branded ranitidine tablets and capsules for Walgreens, respectively, and therefore, Perrigo, Dr. Reddy's, Strides, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Further, based on the limited discovery obtained to date, Plaintiff purchased prescription generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Sandoz and Teva. Thus, Walmart, Walgreens, GSK, Pfizer, BI, Sanofi, Perrigo, Dr. Reddy's, Sandoz, Strides, Teva, and Apotex are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing

Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

129. Plaintiff Ronald Ragan (for the purpose of this paragraph, "Plaintiff"), is a citizen of Colorado. Plaintiff purchased and used Ranitidine-Containing Products in Colorado from approximately 2012 to 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 150 mg Zantac tablets and capsules from approximately 2012 to 2019 (manufactured by BI and Sanofi). Plaintiff also purchased and used OTC 150 mg Walmart-branded and Walgreens-branded ranitidine tablets and capsules purchased from Walmart and Walgreens, respectively, from approximately 2012 to 2019, but based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Perrigo, Dr. Reddy's, Strides, and Apotex manufactured both OTC 150 mg Walmart-branded ranitidine tablets and capsules for Walmart, and Walgreens-branded ranitidine tablets and capsules for Walgreens, and therefore, Perrigo, Dr. Reddy's, Strides, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, Walmart, Walgreens, BI, Sanofi, Perrigo, Dr. Reddy's, Strides, and Apotex are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly

increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

130. Plaintiff Ronald Ragis (for the purpose of this paragraph, "Plaintiff"), is a citizen of Vermont and Florida. Plaintiff purchased and used Ranitidine-Containing Products from approximately 1998 to 2016 as a citizen of Florida. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: (a) OTC 75 mg and 150 mg Zantac tablets and capsules from approximately 1998 to 2016 in Florida as a citizen of Florida (manufactured by GSK, Pfizer, and BI); and (b) OTC 75 mg and 150 mg Walgreens-branded ranitidine tablets and capsules from approximately 2011 to 2016 in Florida as a citizen of Florida. Plaintiff purchased and used additional OTC 75 mg and 150 mg Walgreens-branded ranitidine tablets and capsules from Walgreens in Florida from approximately 2011 to 2016, but based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the Walgreens-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's, Strides, Perrigo, and Apotex manufactured OTC 75 mg and 150 mg Walgreens-branded ranitidine tablets and capsules for Walgreens, and therefore, Dr. Reddy's, Strides, Perrigo, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, GSK, Pfizer, BI, Walgreens, Apotex, Perrigo, Strides, and Dr. Reddy's are "Defendants" with respect to purchases made in Florida while a citizen of Florida, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-

Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

131. Plaintiff Tangie Sims (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arizona. Plaintiff purchased and used Ranitidine-Containing Products in Arizona from approximately 2007 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 150 mg Zantac tablets and capsules from approximately 2007 to 2020 manufactured by BI and Sanofi. Plaintiff also purchased and used OTC Walmart-branded ranitidine tablets and capsules and OTC Walgreens-branded ranitidine tablets and capsules purchased from Walmart and Walgreens, respectively, until approximately 2020 but, based on the limited available sources of information and discovery conducted to date, does not yet know the additional manufacturer(s) of the store-branded ranitidine tablets and capsules. During that time period in question, Dr. Reddy's, Apotex, Strides, and Perrigo manufactured both OTC Walmart-branded ranitidine tablets and capsules for Walmart and OTC Walgreens-branded ranitidine tablets and capsules for Walgreens, and therefore, Dr. Reddy's, Apotex, Strides, and Perrigo are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, Walmart, Walgreens, BI, Sanofi, Dr. Reddy's, Apotex, Strides, and Perrigo are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion,

Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

132. Plaintiff Rebecca Sizemore (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2015 to February 2020 in Indiana. The Ranitidine-Containing Products Plaintiff purchased and used specifically included (a) OTC 75 mg Zantac tablets and capsules from approximately 2015 to February 2020 (manufactured by BI and Sanofi); and (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2015 to February 2020 (manufactured by Sandoz, Strides, and Teva). Plaintiff also purchased and used OTC 75 mg CVS Health-branded ranitidine tablets and capsules from CVS from approximately 2015 to 2020 but, based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's, Strides, and Perrigo manufactured OTC 75 mg CVS Health-branded ranitidine tablets and capsules for CVS, therefore, Dr. Reddy's, Strides, and Perrigo are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, and Glenmark. Thus, BI, Sanofi, Sandoz, Strides, Teva, Perrigo, Amneal, Dr. Reddy's, CVS and Glenmark are "Defendants" for the purposes of

Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

133. Plaintiff Armando Tapia (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arizona. Plaintiff purchased and used Ranitidine-Containing Products in Arizona from approximately 2007 to 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) prescription 150 mg generic ranitidine tablets and capsules from approximately 2007 to 2019 (manufactured by Glenmark, Sandoz, Dr. Reddy's, and Amneal). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Strides, and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

134. Plaintiff Daniel Taylor (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2015 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2015 to 2020 (manufactured by Glenmark). Further, based on the limited discovery obtained to date, Plaintiff purchased and used additional prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Sandoz, Strides, and Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

135. Plaintiff Joyce Taylor (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2010 to February 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included prescription 150 mg generic ranitidine tablets and capsules from approximately 2010 to 2020. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and

Teva. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

136. Plaintiff Michael Tomlinson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2000 to November 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) OTC 150 mg Zantac tablets and capsules from approximately 2014 to 2019 (manufactured by BI and Sanofi); (b) prescription 150 mg (manufactured by Amneal) and 300 mg generic ranitidine tablets and capsules from approximately 2006 to 2019; and (c) prescription 150 mg Zantac tablets and capsules from approximately 2000 to 2002 (manufactured by GSK). Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Plaintiff also purchased and used OTC Walmart-branded ranitidine tablets and capsules purchased from Walmart from approximately 2014 to 2019 but, based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Perrigo, Dr. Reddy's, Strides, and Apotex manufactured OTC Walmart-branded ranitidine tablets and capsules for Walmart, and

therefore, Perrigo, Dr. Reddy's, Strides, and Apotex are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, Walmart, BI, Sanofi, Amneal, GSK, Dr. Reddy's, Glenmark, Sandoz, Strides, Teva, Perrigo, and Apotex are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

137. Plaintiff Chris Troyan (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products in Ohio from approximately 2002 to 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC Zantac tablets and capsules manufactured by Pfizer, BI, and Sanofi. Plaintiff also purchased and used OTC CVS-branded ranitidine tablets and capsules purchased from CVS from approximately 2011 to 2020 but, based on the limited available sources of information and discovery conducted to date, does not yet know the specific manufacturer(s) of the store-branded ranitidine tablets and capsules. During the time period in question, Dr. Reddy's, Strides, and Perrigo manufactured OTC CVS-branded ranitidine tablets and capsules for CVS; and therefore, Dr. Reddy's, Perrigo, and Strides are named as Defendants until adequate information is produced to identify the specific entity(ies) that manufactured the store-branded ranitidine tablets and capsules purchased by Plaintiff. Thus, CVS, Pfizer, BI, Sanofi, Dr. Reddy's, Perrigo, and Strides

are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

138. Plaintiff Sharon Tweg (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2010 to June 2018. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 150 mg Zantac tablets and capsules in approximately 2010 to 2018 (manufactured by BI and Sanofi). Thus, BI and Sanofi are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

139. Plaintiff Angel Vega (for the purpose of this paragraph, "Plaintiff"), is a citizen of Montana. Plaintiff purchased and used Ranitidine-Containing Products in Montana from approximately 2011 to 2016. The Ranitidine-Containing Products purchased and used by Plaintiff

specifically included OTC Zantac tablets and capsules from approximately 2015 to 2016, manufactured by BI. Thus, BI is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

140. Plaintiff Gustavo Velasquez (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2000 to February 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 75 and 150 mg Zantac tablets and capsules from approximately 2000 to 2020 (manufactured by Pfizer, BI, and Sanofi). Thus, Pfizer, BI, and Sanofi are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

141. Plaintiff Teresa Waters (for the purpose of this paragraph, "Plaintiff"), is a citizen

of Utah. Plaintiff purchased and used Ranitidine-Containing Products in Utah from approximately 2017 to March 2020. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: (a) prescription 150 mg generic ranitidine tablets and capsules from approximately 2017 to 2020; and (b) OTC 150 mg Zantac tablets and capsules from approximately 2017 to 2020 (manufactured by BI and Sanofi). Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 150 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Amneal, Dr. Reddy's, Glenmark, Sandoz, and Strides. Thus, BI, Sanofi, Amneal, Dr. Reddy's, Glenmark, Sandoz, and Strides are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

142. Plaintiff Tracy Wells (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2013 to 2019 in Indiana. The Ranitidine-Containing Products Plaintiff purchased and used specifically included the following: (a) OTC 150 mg Zantac tablets and capsules from approximately 2013 to 2019 (manufactured by BI and Sanofi); and (b) prescription 300 mg generic ranitidine tablets and capsules from approximately 2013 to 2019. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 300 mg generic ranitidine tablets and capsules

manufactured by one or more of the following defendants: Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva. Thus, BI, Sanofi, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

143. Plaintiff Darlene Whittington-Coates (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2017 to October 2019 in Maryland. The Ranitidine-Containing Products Plaintiff purchased and used specifically included prescription 300 mg generic ranitidine tablets and capsules from approximately 2017 to October 2019, manufactured by Amneal. Further, based on the limited discovery obtained to date, Plaintiff purchased and used prescription 300 mg generic ranitidine tablets and capsules manufactured by one or more of the following defendants: Dr. Reddy's, Glenmark, Sandoz, and Strides. Thus, Amneal, Dr. Reddy's, Glenmark, Sandoz, and Strides are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly

increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

144. Plaintiff Joshua Winans (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida from approximately 2000 to 2019. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 75 and 150 mg Zantac tablets and capsules from approximately 2000 to 2019 (manufactured by Pfizer, BI, and Sanofi). Thus, Pfizer, BI, and Sanofi are "Defendants" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming these Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed these Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of Defendants' wrongful conduct.

IV. FACTUAL ALLEGATIONS

A. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET

145. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the Brand Zantac or a generic equivalent by either prescription or OTC.

1. GSK Develops Zantac Through a Flurry of Aggressive Marketing Maneuvers

146. Ranitidine belongs to a class of medications called histamine H_2-receptor

antagonists (or H_2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

147. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H_2 blocker and the prototypical histamine H_2 receptor antagonist from which the later members of the class were developed.

148. GSK[23] developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H_2 blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

149. In 1976, scientist John Bradshaw, on behalf of GSK-predecessor Allen & Hanburys Ltd. synthesized and discovered ranitidine.

150. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

151. In 1983, the FDA granted approval to GSK to sell Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product—a "blockbuster." Indeed, Zantac became the first prescription drug in history to reach $1 billion in sales.

152. To accomplish this feat, GSK entered into a joint promotion agreement with

[23] GSK, as it is known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

Hoffmann-LaRoche, Inc., [redacted].[24] More salespersons drove more sales and blockbuster profits for GSK.

153. In June 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease ("GERD").

154. In December 1993, GSK (through Glaxo Wellcome plc) entered into a partnership agreement with Pfizer-predecessor company Warner-Lambert Co. to develop and market an OTC version of Zantac.[25] In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC Zantac 75 mg effervescent tablets through NDA 20-745.

155. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their partnership. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK retained rights to sell OTC Zantac outside of the United States and Canada,[26] and retained control over the Zantac trademark internationally.[27]

156. In 2000, Pfizer acquired Warner-Lambert Co. Pfizer controlled the Zantac OTC NDAs until December 2006.

157. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the

[24] GSKZAN0000348881; GSKZAN0000348871
[25] GSKZAN0000022775.
[26] GSK also still held the right to sell prescription Zantac in the United States.
[27] PFI00245109.

approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription Ranitidine-Containing Product in the United States.

158. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA approved NDA 21-698 on August 31, 2004.

159. During the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

160. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson & Johnson ("J&J").[28] Because of antitrust issues, however, Zantac was transferred to Boehringer Ingelheim.

161. Pfizer, through a divestiture agreement, transferred all assets pertaining to its Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, research and development, and customer and supply contracts to Boehringer Ingelheim.

162. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the Zantac OTC NDAs.

163. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making

[28] PFI00191352.

and selling prescription Zantac tablets in 2017 . . . in the U.S."[29]

164. Boehringer Ingelheim owned and controlled the NDA for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.[30]

165. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer Ingelheim continued to manufacture OTC Zantac for Sanofi.

166. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a global recall and ceased marketing, selling, and distributing OTC Zantac. In addition, Sanofi has marketed, sold, and distributed ranitidine globally since 1983.[31]

167. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

168. Sanofi voluntarily recalled all Brand OTC Zantac and ranitidine on October 18, 2019.

169. Pfizer and Boehringer Ingelheim have made demands for indemnification per the Stock and Asset Purchase Agreement against J&J for legal claims related to OTC Zantac products.

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[29] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.
[30] Boehringer Ingelheim also owned and controlled ANDA 074662.
[31] SANOFI_ZAN_MDL_0000208478.

170. Sanofi has made a demand for indemnification against J&J pursuant to a 2016 Asset Purchase Agreement between J&J and Sanofi.

171. The times during which each Brand Manufacturer Defendant manufactured and sold branded Zantac are alleged below:

Manufacturer/ Repackager	Product	Prescription or Over the Counter	Sale Start Date Year	Sale End Date Year
GlaxoSmithKline	Pills, Syrup, and Injection	Prescription	1983	2019
Pfizer	Pills	OTC	1998	2006
Boehringer Ingelheim	Pills	OTC	2007	2016
Sanofi	Pills	OTC	2017	2019

2. Patents Expire, Allowing Prescription and Later, OTC Generics (and Store Brands) to Enter the Market

172. In 1997, GSK's patent on the original prescription Zantac product expired, allowing generic manufacturers to sell prescription ranitidine.

173. When GSK and Pfizer's patent on the original OTC Zantac product expired, generic manufacturers and store-brand retailers were allowed to sell OTC ranitidine.

174. The FDA approved numerous generic and store-brand manufacturers for the sale of prescription and OTC ranitidine through the ANDA process. Those generic manufacturers who are named in this medical monitoring complaint are:

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	Sold Until	OTC/RX
76124	Actavis Mid Atlantic LLC	EQ 15 mg Base/ml	Syrup; Oral	2/21/07	03/2015	Discontinued
77824	Amneal Pharmaceuticals of New York, LLC	EQ 150 & 300 mg Base	Tablet; Oral	10/13/06	11/2019	Discontinued

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	Sold Until	OTC/RX
78312	Amneal Pharmaceuticals	EQ 150 & 300 mg Base	Syrup; Oral	9/2/08	11/2019	Rx
200172	Apotex Inc.	EQ 150 mg Base	Tablet; Oral	5/31/12	09/2019	OTC
74680	Apotex Inc.	EQ 150 & 300 mg Base	Tablet; Oral	9/12/97	09/2010	Rx
75167	Apotex Inc.	EQ 75 mg Base	Tablet; Oral	5/4/00	09/2019	OTC
77602	Apotex Inc.	EQ 15 mg Base/ml	Syrup; Oral	9/17/07	08/2009	Discontinued
74662	Boehringer Ingelheim	EQ 150 & 300 mg Base	Tablet; Oral	8/29/97		Discontinued
75294	Dr Reddy's Laboratories Ltd.	EQ 75 mg Base	Tablet; Oral	3/28/00	09/2019	OTC
75742	Dr Reddy's Laboratories Ltd.	EQ 150 & 300 mg Base	Capsule; Oral	11/29/00	09/2019	Rx
76705	Dr Reddy's Laboratories Inc.	EQ 150 & 300 mg Base	Tablet; Oral	7/27/05	09/2019	Rx
78192	Dr Reddy's Laboratories Ltd.	EQ 150 mg Base	Tablet; Oral	8/31/07	09/2019	OTC
78542	Glenmark Pharmaceuticals, Inc., USA	EQ 150 & 300 mg Base	Tablet; Oral	11/19/08	Various dates between 08-2019 and 10/2019	Rx
76195	L. Perrigo Co.	EQ 75 mg Base	Tablet; Oral	8/30/02	Various dates between 04/2007 and 10/2019	OTC
91429	Perrigo Research & Development Company	EQ 150 mg Base	Tablet; Oral	5/11/11	10/2019	OTC
74467	Sandoz Inc.	EQ 150 & 300 mg	Tablet; Oral	8/29/97	09/2017	Rx

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	Sold Until	OTC/RX
		Base				
74655	Sandoz Inc.	EQ 150 & 300 mg Base	Capsule; Oral	10/22/97	09/2019	Rx
75519	Sandoz Inc.	EQ 75 mg Base	Tablet; Oral	9/26/02	On information and belief, on or before 04/2020	Discontinued
200536	Strides Pharma Global Pte Ltd	EQ 150 mg Base	Tablet; Oral	6/28/11	10/2017	OTC
201745	Strides Pharma Global Pte. Ltd.	EQ 75 mg Base	Tablet; Oral	2/29/12	12/2017	OTC
205512	Strides Pharma Global Pte. Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	8/22/16	03/2020	Rx
209160	Strides Pharma Global Pte. Ltd.	EQ 75 mg Base	Tablet; Oral	3/5/18	09/2018	OTC
209161	Strides Pharma Global Pte. Ltd.	EQ 150 mg Base	Tablet; Oral	2/22/18	09/2018	OTC
210010	Strides Pharma Global Pte Ltd	EQ 150 & 300 mg Base	Tablet; Oral	8/1/18	On information and belief, 04/2020	Rx
74488	Teva Pharmaceuticals USA, Inc.	150 mg & 300 mg	Tablet; Oral		2/2008	Rx
074864	Watson Laboratories, Inc.	150 mg & 300 mg	Tablet; Oral		10/2015	Rx
075165	IVAX Pharmaceuticals Inc Sub Teva Pharmaceuticals USA, Inc.	150 mg & 300 mg	Tablet; Oral		9/2016	Rx
075296	IVAX Pharmaceuticals Inc Sub Teva Pharmaceuticals USA, Inc.	75 mg	Tablet; Oral		1/2008	OTC
076124	Actavis Mid Atlantic LLC	15 mg/ml	Syrup		3/2015	Rx

175. "An abbreviated new drug application (ANDA) contains data which is submitted

to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the Brand drug it references."[32]

176. Generic (and store-brand) drugs must be comparable to the branded drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use.[33]

177. ANDA applicants generally do not need to establish safety and effectiveness. Instead, applicants must scientifically demonstrate that their product performs in the same manner as the innovator drug, known as "bioequivalence."

178. Once a manufacturer's ANDA is approved, that manufacturer is subject to post-market obligations. These obligations include submitting annual reports to the FDA, tracking and reporting adverse events, and tracking and reporting relevant medical literature, among other things.

179. These ANDA approvals allowed the Generic Manufacturer Defendants and Store-Brand Defendants to sell their ranitidine products throughout the country. And they did so.

180. All Defendants who have the power of labeling and listing drugs within the United States must obtain a National Drug Code ("NDC"). All NDC holders are required to register all drugs and list them with the FDA.

181. All Defendants who have registered establishments with the FDA must provide "[c]omplete, accurate and up-to-date establishment registration and drug listing information [which] is essential to promote patient safety. FDA relies on establishment registration and drug

[32] https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda. U.S. Food & Drug Admin., *Abbreviated New Drug Application (ANDA)* (May 22, 2019).
[33] *Id.*

listing information for several key programs, including:

- Drug establishment inspections
- Post market surveillance
- Counterterrorism
- Recalls
- Drug quality reports
- Adverse event reports
- Monitoring of drug shortages and availability
- Supply chain security
- Drug import and export
- Identification of products that are marketed without an approved application"[34]

182. In registering with the FDA to manufacture, label, distribute, and sell Ranitidine-Containing Products within all states and territories of the United States, all Defendants holding an ANDA, NDC or which registered an establishment had an obligation to comply with federal law.

183. Based upon the information provided by Defendants to date, the following Generic Prescription Defendants and Store-Brand Defendants manufactured Ranitidine-Containing Products during the following date ranges. Upon information and belief, each Defendant began researching Ranitidine-Containing Products at least one year prior to the date they commenced selling the product and, therefore, knew or should have known of all risks associated with Ranitidine-Containing Products discussed herein from that date onward:

Manufacturer/ Repackager (by Corporate Family)	**Product**	**Prescription or Over the Counter**	**Sale Start Date Year**	**Sale End Date Year**
Apotex	Pills and Syrup	Prescription	1997	2019
Sandoz	Pills	Prescription	1997	2019
Teva	Pills and Syrup	Both	1998	2016
Perrigo	Pills	OTC	2000	2019

[34] U.S. Food & Drug Admin., *Electronic Drug Registration and Listing System (eDRLS)* (Dec. 18, 2020) https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls.

Manufacturer/ Repackager (by Corporate Family)	Product	Prescription or Over the Counter	Sale Start Date Year	Sale End Date Year
Dr. Reddy's	Pills	Both	2005	2019
Amneal	Pills and Syrup	Prescription	2009	2019
Glenmark	Pills	Prescription	2009	2019
Strides	Pills	Both	2012	2020

184. Despite generic entry, the Brand Manufacturer Defendants continued to sell prescription and OTC Zantac. Although sales of Zantac declined as a result of generic competition, ranitidine sales remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablets in the United States, with sales of OTC Zantac 150 totaling $128.9 million – a 3.1% increase from the previous year.

3. NDMA Is a Carcinogen Whose Dangerous Properties Are Well Established

185. According to the Environmental Protection Agency ("EPA"), NDMA is a semivolatile organic chemical that forms in both industrial and natural processes."[35] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[36] NDMA is no longer

[35] U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (*Nov*. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[36] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

186. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.[37]

187. The IARC classification is based upon data that demonstrates NDMA "is carcinogenic in all animal species tested: mice, rats, Syrian gold, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, various fish, newts and frogs. It induces benign and malignant tumors following its administration by various routes, including ingestion and inhalation, in various organs in various species." Further, in 1978, IARC stated that NDMA "should be regarded for practical purposes as if it were carcinogenic to humans."[38]

188. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[39]

189. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[40] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[41]

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[37] *See* EPA Technical Fact Sheet, *supra*, note 35; Int'l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

[38] 17 Int'l Agency for Research on Cancer, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds* 151–52 (May 1978).

[39] *See* EPA Technical Fact Sheet, *supra* note 35.

[40] *Id*. at 3.

[41] *Id*.

190. The FDA considers NDMA a carcinogenic impurity[42] and chemical that "could cause cancer" in humans.[43] The FDA recognizes that NDMA is "known to be toxic."[44]

191. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[45] NDMA belongs to the so-called "cohort of concern" which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.[46]

192. NDMA is among the chemicals known to the State of California to cause cancer (Title 27, California Code of Regulations, Section 27001), pursuant to California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

193. The European Medicines Agency "(EMA") has referred to NDMA as "highly carcinogenic." It recommended that "primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines" (including NDMA), and categorized NDMA as "of highest concern with respect to mutagenic and carcinogenic potential."[47]

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[42] ApotexCorp_0000000786.

[43] FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[44] Amneal_prod 1 _ 0000002938.

[45] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

[46] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1), March 2017; https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf.

[47] Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf.

194. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is "reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans" and that the "carcinogenicity of orally administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies" in animals and "it is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." Moreover, "hepatoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who were exposed to NDMA by ingestion or inhalation." [48]

195. The International Register of Potentially Toxic Chemicals (IRPTC 1988) lists regulations imposed by 13 countries for NDMA for occupational exposure, packing, storing and transport, disposal, and warns of its probable human carcinogenicity and its high level of toxicity by ingestion or inhalation.

196. The Occupational Safety and Health Administration classifies NDMA as "a carcinogen" that requires special and significant precautions along with specific hazard warnings.[49]

197. A review of Defendants' own internal documents reveals that there is simply no question of material fact that it has been widely known within the medical and scientific community for over 40 years that NDMA is toxic and a known carcinogen.

198. In September 2019, Defendant GSK [redacted]

[48] ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[49] 29 C.F.R §1910.1003 (2012).

[redacted].”[50] In addition, GSK [redacted] *Id.* GSK [redacted] *Id.*

199. [redacted].[51] [redacted][52] [redacted].[53]

200. [redacted]

[50] GSKZAN0000236640.
[51] GSKZAN0000369506.
[52] GSKZAN0000257640.
[53] *Id.*

[redacted].[54] [redacted].[55] [redacted]."[56] [redacted] [57]

201. Likewise, Defendant Sanofi [redacted]."[58] [redacted] [59] [redacted] *Id.*

202. Dr. Reddy's [redacted] [60] [redacted]

[54] GSKZAN0000163882.
[55] *See* GSK Dear HCP Letter, (October 3, 2019), publicly available (for example, https://www.hpra. ie/docs/default-source/Safety-Notices/gsk-hcp-letter-03oct2019.pdf).
[56] GSKZAN0000178581.
[57] GSKZAN0000172037.
[58] SANOFI_ZAN_MDL_0000169790.
[59] SANOFI_ZAN_MDL_0000206858.
[60] DRLMDL0000077291.

[redacted][61] [redacted][62].

203. [redacted]

Id.

204. Defendant Apotex [redacted].”[64]

205. Defendant Glenmark admits in its recall notification letter that “a carcinogenic

[61] DRLMDL0000070414.
[62] *Id*.
[63] DRLMDL0000069991.
[64] ApotexCorp_0000030734.

impurity, NDMA, has been found in ranitidine medications at levels exceeding the FDA allowable limit."[65]

206. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

207. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure – Valsartan, Losartan, and Irbesartan – because the medications contained nitrosamine impurities that do not meet the FDA's safety standards. Some of the manufacturers of those contaminated medications also are parties to this case. They include Sandoz and Teva.

208. This continued in 2020 when the FDA required recalls of numerous generic manufacturers' metformin, including metformin made by Apotex, Amneal, Granules, Sun Pharmaceuticals, Nostrum, and Teva.[66]

209. NDMA is a genotoxin which interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

210. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure

[65] GiantEagle_MDL2924_00000303.

[66] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Metformin* (Jan. 6, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin.

increases. However, any level above 96 ng is considered unacceptable.[67]

211. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, cancers were observed in the liver, pancreas, and stomach. In comparable guinea-pig studies, cancers were observed in the liver and lung. In comparable rabbit studies, cancers were observed in the liver and lung.

212. In other long-term animal studies in mice and rats utilizing different routes of exposures – inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) – cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

213. Prior to the withdrawal of ranitidine, it was considered a category B drug for birth defects, meaning it was considered safe to take during pregnancy. Yet animals exposed to NDMA during pregnancy birthed offspring with elevated rates of cancer in the liver and kidneys.

214. NDMA is a very small molecule. That allows it to pass through the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

215. Exposure to high levels of NDMA has been linked to liver damage in humans.[68]

216. Numerous *in vitro* studies confirm that NDMA is a mutagen – causing genetic mutations in human and animal cells.

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[67] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

[68] *See* EPA Technical Fact Sheet, *supra* note 35.

217. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

218. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[69]

219. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[70]

220. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. These studies consistently show increased risks of various cancers.

221. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 micrograms/day.[71]

222. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 micrograms/day.[72]

223. In another 1995 epidemiological case-control study looking at, in part, the effects

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[69] *Id.*

[70] *See* U.S. Envtl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

[71] Pobel et al., *Nitrosamine, Nitrate and Nitrite in Relation to Gastric Cancer: A Case-control Study in Marseille, France*, 11 Eur. J. Epidemiol. 67-73 (1995).

[72] La Vecchia, *et al.*, *Nitrosamine Intake & Gastric Cancer Risk*, 4 Eur. J. Cancer Prev. 469-74 (1995).

of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 micrograms/day.[73]

224. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "*N*-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[74]

225. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.[75]

226. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[76]

227. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 1,760 cases, researchers found a statistically significant elevated association between NDMA exposure and rectal cancer.[77]

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[73] Rogers et al., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cancer*, 5 Cancer Epidemiol. Biomarkers Prev. 29–36 (1995).

[74] Knekt et al., *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study*, 80 Int. J. Cancer 852–56 (1999).

[75] Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 Occup. Envtl. Med 180–87 (2000).

[76] Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 Am. J. Clinical Nutrition 1053–61 (2011).

[77] Zhu et al., *Dietary N-nitroso Compounds and Risk of Colorectal Cancer: A Case-control Study in Newfoundland and Labrador and Ontario, Canada*, 111 Brit. J. Nutrition 6, 1109–17 (2014).

228. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro.* However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[78]

229. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (a:) can exacerbate existing but dormant (*i.e.*, not malignant) tumor cells; (b) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (c) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

4. NDMA Is Discovered in Ranitidine-Containing Products, Leading to Market Withdrawal

230. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all Ranitidine-Containing Products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[79] This set off a cascade of recalls by Defendants.

[78] World Health Org., *supra* note 45.

[79] FDA Statement, Woodcock, *supra* note 43; Press Release, European Medicines Agency, *EMA to Review Ranitidine Medicines Following Detection of NDMA* (Sept. 13, 2019), https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma.

231. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.[80]

232. On September 24, 2019, Sandoz voluntarily recalled all of its Ranitidine-Containing Products due to concerns of a "nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine."[81]

233. On September 26, 2019, Apotex, Walgreens, Walmart, and Rite Aid voluntarily recalled all ranitidine products and removed them from shelves.[82] Apotex issued a statement, noting that "Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)."[83]

234. On September 28, 2019, CVS stated that it would stop selling Zantac and its CVS Health Store-Brand ranitidine out of concern that it might contain a carcinogen.

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[80] FDA Statement, Woodcock, *supra* note 43.

[81] FDA News Release, U.S. Food & Drug Admin., *FDA Announces Voluntary Recall of Sandoz Ranitidine Capsules Following Detection of an Impurity* (Sept. 24, 2019), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity.

[82] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Sept. 26, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[83] Company Announcement, U.S. Food & Drug Admin., *Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All Pack Sizes and Formats) Due to the Potential for Detection of an Amount of Unexpected Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Sept. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and.

235. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer ("LC-HRMS") testing protocol, which "does not use elevated temperatures."[84]

236. On October 8, 2019, GSK voluntarily recalled all Ranitidine-Containing Products internationally.[85] As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GSK is continuing with investigations into the potential source of the NDMA."[86]

237. On October 18 and 23, 2019, Sanofi and Dr. Reddy's voluntarily recalled all of their Ranitidine-Containing Products.[87]

238. On October 28, 2019, Perrigo voluntarily recalled all of its Ranitidine-Containing Products.[88]

239. In its recall notice, Perrigo stated, "[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality

[84] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[85] Press Release, Gov. UK, *Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls All Unexpired Stock* (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[86] Justin George Varghese, *GSK Recalls Popular Heartburn Drug Zantac Globally After Cancer Scare*, Reuters (Oct. 8, 2019), https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL.

[87] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[88] *Id*.

of data gathered to date, Perrigo has made the decision to conduct this voluntary recall."[89]

240. On November 1, 2019, the FDA announced the results of recent testing, finding unacceptable levels of NDMA in Ranitidine-Containing Products, and requested that drug makers begin to voluntarily recall their Ranitidine-Containing Products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[90]

241. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite.[91] This advice ***mirrored*** an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. Silvio de Flora published in October 1981 in *The Lancet* was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbic acid."[92] If GSK had only heeded Dr. de Flora's advice in 1981, millions of people might have avoided exposure to NDMA formed as a result of ranitidine's interaction with the human digestive system.

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[89] Company Announcement, U.S. Food & Drug Admin., *Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n.

[90] U.S. Food & Drug Admin., Laboratory Tests | Ranitidine, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (content current as of Nov. 1, 2019).

[91] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Dec. 4, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[92] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993-94.

242. Between November 1, 2019, and February 27, 2020, Amneal and Glenmark recalled their products from the market, citing NDMA concerns.[93]

243. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-liable and under certain temperatures progressively accumulates NDMA.

244. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that "by-products that are probable carcinogens can be generated if exposed to heat." In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.[94]

245. In response,[95] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[96] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of

[93] *See generally* U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (content current as of Apr. 16, 2020).

[94] Emery Pharma FDA Citizen Petition (Jan. 2, 2020) https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

[95] Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.

[96] *Id*. at 5 (*citing* 21 CFR 7.40(a)).

injury."[97] The FDA found that the recall of all Ranitidine-Containing Products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk."[98] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[99]

246. The FDA found its stability testing raised concerns that NDMA levels in some Ranitidine-Containing Products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any Ranitidine-Containing Product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency's laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

247. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned Ranitidine-Containing Products.[100]

248. The European Medicines Agency ("EMA"), the Union's EU equivalent to the FDA, through an Article 31 Referral, determined the sale of all Ranitidine-Containing Products should

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[97] *Id*.
[98] *Id*. at 7.
[99] *Id*. at 10 n.43.
[100] Margaret Newkirk & Susan Berfield, *FDA Recalls Are Always Voluntary and Sometimes Haphazard – and The Agency Doesn't Want More Authority to Protect Consumers*, Bloomberg Businessweek (Dec. 3, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[101]

249. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA noting that it is a probable human carcinogen and that there is evidence that NDMA forms from the degradation of ranitidine itself with increasing levels seen over shelf life.[102]

B. THE SCIENCE

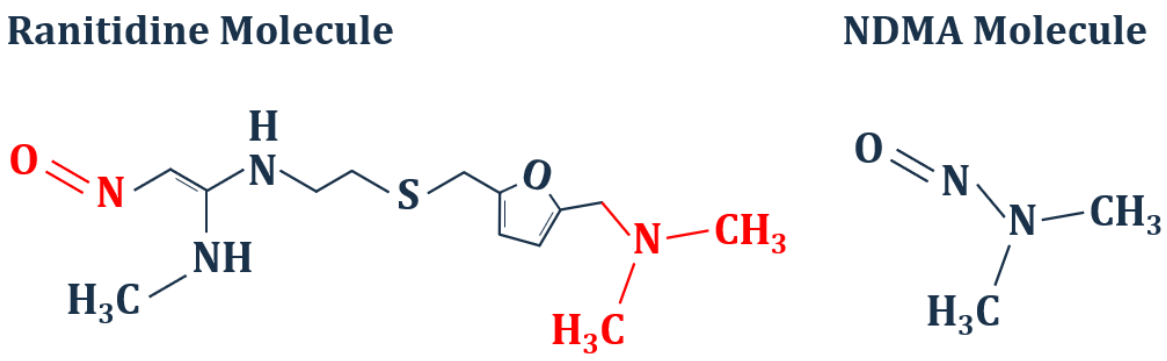
1. How Ranitidine Transforms into NDMA

250. The ranitidine molecule itself contains the constituent molecules to form NDMA. *See* Figure 1.

[101] Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf.

[102] Eur. Med. Agency, EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU (Nov. 24, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



251. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

252. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply.[103] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.[104]

253. The high levels of NDMA observed in Ranitidine-Containing Products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

[103] Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).
[104] Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389–404 (2003).

2. Formation of NDMA in the Environment of the Human Stomach

254. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H_3C-N-CH_3) break off and reform as NDMA.

255. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The Lancet*. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects."[105] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to . . . suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."[106] *Id*.

256. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in *The Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.[107]

257. This response reflects GSK's reputation for "adopting the most combative,

[105] De Flora, *supra* note 92.

[106] This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. So GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

[107] R. T., Brittain et al., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

scorched-earth positions in defense of its brands."[108] The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

258. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into the company's outrageous misbehavior,[109] GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data in the country's history.[110] There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government information about the potential presence of NDMA in Zantac.[111]

259. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to

[108] Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) https://www.cbsnews.com/news/gsks-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/.

[109] *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong.2d Sess. 1 (Comm. Print Jan. 2010).

[110] U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

[111] Sanofi, Half-Year Financial Report (2020), https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020_07_29_HY_financial_report_EN.pdf.

ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.[112]

260. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NMDA.[113]

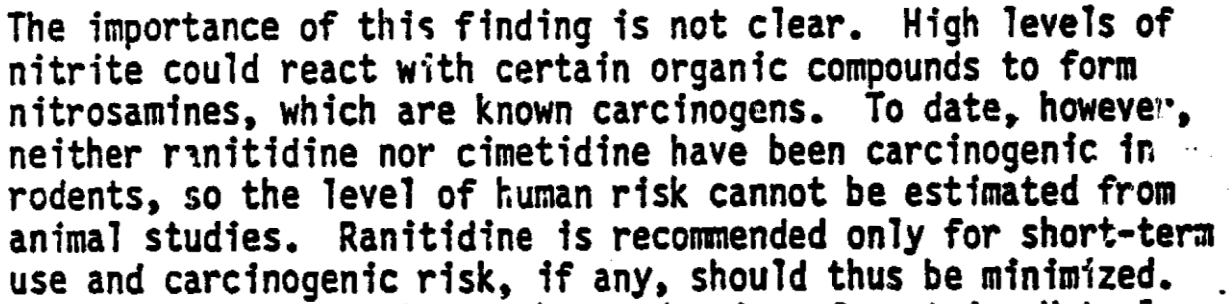
261. In its submission to the FDA, GSK discussed its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent mutagen, but explained that these results had no "practical clinical significance"[114]:

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

262. In 1980 – before Zantac was approved by the FDA – GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.[115] Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were

[112] GSKZAN0000050413.
[113] GSKZNDAA0000071900.
[114] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.
[115] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

allegedly only expected to use Ranitidine-Containing Products for a short-term period:


The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

263. GSK knew – and indeed specifically admitted – that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew, but did not disclose, that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

264. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[116] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."[117] In other words, GSK intentionally engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

[116] Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).
[117] *Id*.

265. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

266. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[118] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells." *Id.*

267. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[119] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GSK's studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

268. In addition, as multiple Defendants have noted in internal documents and recent submissions to regulatory authorities, a mechanism for ranitidine to form NDMA [redacted]

[118] Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Lttrs. 97-102 (1983).
[119] De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255-60 (1983).

[redacted]

[redacted].[120] Therefore, this potential mechanism was disregarded.

269. [redacted]

[redacted].[121]

270. However, in 1985 GSK [redacted].[122] [redacted]

[120] SANOFI_ZAN_MDL-0000033849-SANOFI_ZAN_MDL_0000033891, at SANOFI_ZAN_MDL_0000033873.

[121] GSKZNDAA0000072103-GSKZNDAA0000072128.

[122] GSKZAN0000369313, ([redacted]

[redacted][123]

[redacted]

271. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[124] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

272. In 2002, researchers conducted a controlled study to evaluate the concentration of nitrosamines, including NDMA, in the gastric fluid and urine in children with gastritis before and after four to six weeks of treatment with ranitidine. The study reported statistically significant increases in the nitrosamine concentration, including NDMA, in the gastric juice and urine in 93.3% of children after taking ranitidine for only four weeks. The researchers noted that nitrosamines belong to the most potent known carcinogens and no organisms have been found that would be resistant to the harmful effects, that neoplastic lesions induced by nitroso compounds may develop in any organ, and that nitrosamines induced a wide spectrum of tumors in studies using animal models. In addition, the authors noted specifically that NDMA induced similar

[123] GSKZNDAA0000636549.

[124] Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 Envtl. Sci. Tech. 20, 11095-103 (2012).

symptoms of acute poisoning in humans and animals. They advised that prophylactic measures to avoid nitrosamine formation include a diet high in fruits and inclusion of ascorbic acid as well as limiting intake of processed meat. The conclusion was that ranitidine should only be recommended in children after careful consideration.[125]

273. Despite the direct evidence that children taking ranitidine were being exposed to dangerously high levels of carcinogenic nitrosamines including NDMA, Defendants recklessly continued to market and promote Zantac and/or ranitidine as safe and effective for children.

274. Similarly, in 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers. They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed that ranitidine generates NDMA in the human body.[126]

275. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market.

[125] Krawczynski, et al. *Nitrosamines in Children with Chronic Gastritis*, Journal of the Polish Pediatric Society (GSKZAN0000235261).

[126] Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 Carcinogenesis 625–34 (2016).

In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

276. In its September 9, 2019, Citizen's Petition to the FDA, [127] Valisure disclosed as part of its testing of Ranitidine-Containing Products that in every lot tested there were exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[128] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

[127] Valisure, *Citizen Petition on Ranitidine* (Sept. 9, 2019), *available at* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf.

[128] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

277. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

278. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

279. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF": 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF": 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

280. Indeed, Ranitidine-Containing Products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[129]

281. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

[129] *See, e.g.*, Zantac television commercial, *Family Taco Night*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; Zantac television commercial, *Spicy*, https://youtu.be/jzS2kuB5_wg; Zantac television commercial, *Heartburn*, https://youtu.be/Z3QMwkSUlEg; Zantac television commercial, *Zantac Heartburn Challenge*, https://youtu.be/qvh9gyWqQns.

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation

Ranitidine Tablet Studies	NDMA (ng/mL)	NDMA per tablet (ng)
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid ("SIF")	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

282. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg ranitidine, ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg ranitidine at the 25 nanogram level (over 7,000 for the 50 nanogram level).

283. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed SGF and SIF models to use with the LC-MS testing method to estimate the biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

284. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant levels of nitrite in the stomach – a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month – the ranitidine molecule transforms into more NDMA which would dramatically increase a person's risk of

developing cancer.

3. Formation of NDMA in Other Organs of the Human Body

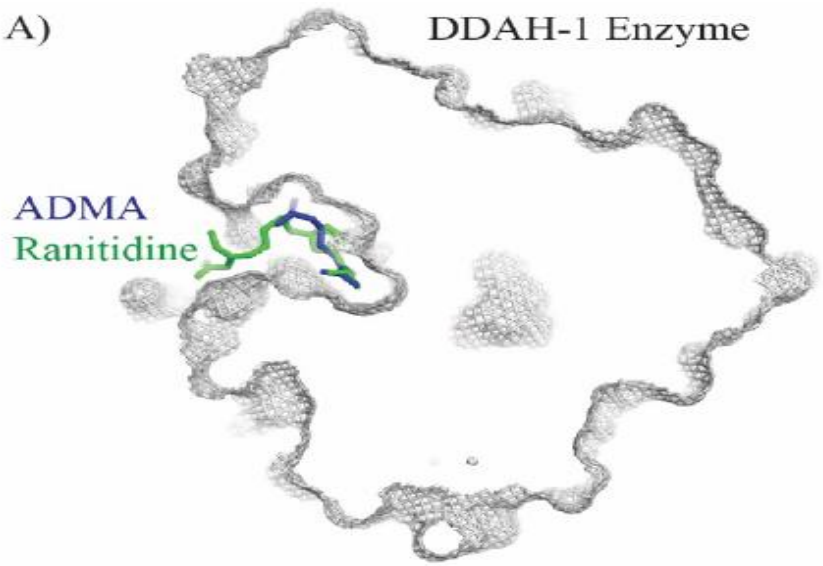
285. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

286. Valisure explained that liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[130]

[130] Ogawa, *et al.*, *supra* note 103.

287. Valisure reported as illustrated in Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme



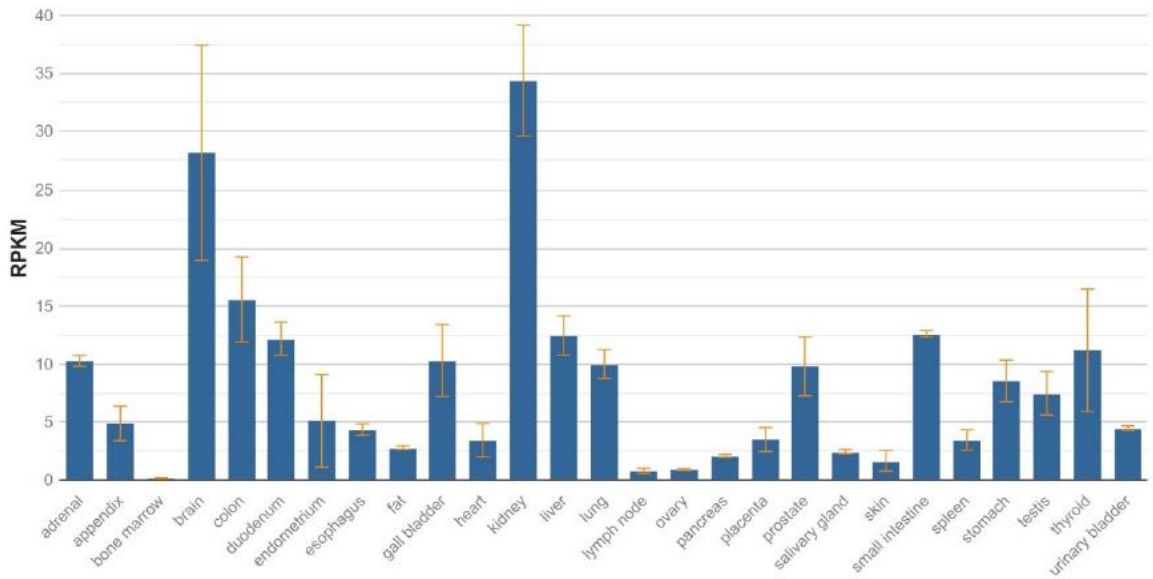
B)

	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

288. Valisure reported that these results suggest that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

289. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



290. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that this offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs.

291. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford

study, discussed above.

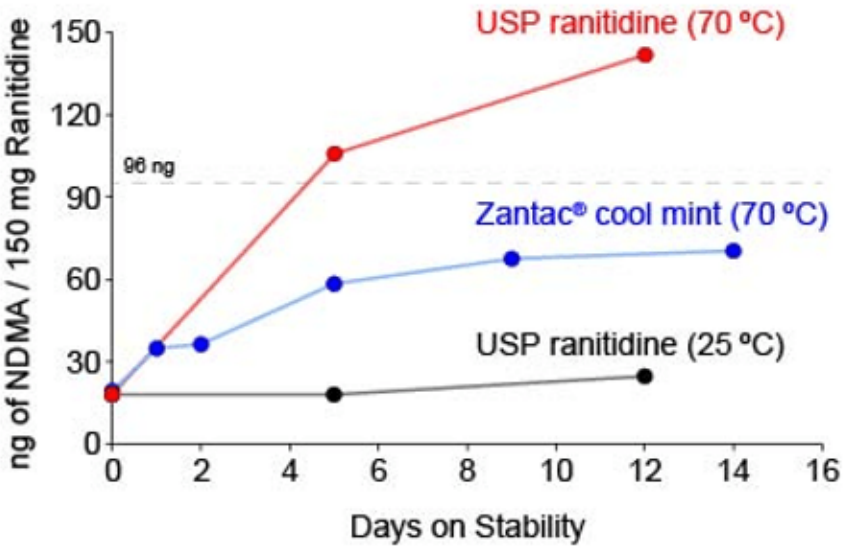
4. Formation of NDMA by Exposure to Heat, Moisture, and/or Time

292. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high heat testing method.

293. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

294. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ◦C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. As reported by Emery Pharma, the following diagram reveals how NDMA accumulates over time when exposed to 70 ◦C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



295. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.[131]

296. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering Ranitidine-Containing Products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real – a point underscored by the FDA's swift removal of the product from the market.

[131] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), *available at* https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

297. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.[132]

298. In 2019, the findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all Ranitidine-Containing Products from the market.

299. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

300. After undertaking an investigation, GSK concluded that "the presence of NDMA in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the dimethylamino group, are both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule."[133] Unsurprisingly, GSK [redacted]"[134] In addition, GSK's [redacted].[135]

[132] Woodcock Letter, *supra* note 95.
[133] GSKZAN0000052019-GSKZAN0000052127
[134] *Id*. p. 2.
[135] *Id*. p. 12.

301. Similarly, [redacted].”[136]

302. [redacted][137]

303. Defendants could dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

304. Based upon the documents produced by Defendants and based upon further information and belief, Defendants failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.[138]

5. Evidence Directly Links Ranitidine to Cancer

305. In addition to numerous epidemiology studies examining how NDMA causes

[136] SANOFI_ZAN_MDL_0000151458

[137] SANOFI_ZAN_MDL_0000166517-527, at p. 11.

[138] *See, e.g.,* BOE_ZAN_MDL_0000203482 (“[redacted]”); GSKZAN0000178835 ([redacted]”); DRLMDL0000087754 [redacted]); DRLMDL0000077957 ([redacted]).

cancer in humans, researchers have also specifically looked at ranitidine and found an association with cancer.

306. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[139]

307. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk, an effect that was even more pronounced in those with specific gene mutations.[140]

308. In another epidemiological study looking at various cancer risks and histamine H_2-receptor antagonists (or H_2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer. Of particular note, the study indicated that people under the age of 60 who took ranitidine were five times more likely to develop prostate cancer. In addition, there was more than a doubling of the risk of pancreatic cancer with ranitidine use.[141]

309. A study published in 2018, demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other H_2 blockers in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This

[139] D. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 Cancer Epi. Biomarkers & Prevention 250-54 (Feb. 2004).
[140] Robert W. Mathes et al., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Prevention 1, 67-72 (2008).
[141] Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149–55 (2000).

finding is particularly notable as the authors adjusted for variables.[142]

310. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H_2 blockers.[143] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H_2 blockers as a confounder. The study only considered use of H_2 blockers within one year of cancer diagnosis and still found an increased odds ratio associated with use of H_2 blockers and hepatocellular carcinoma, a type of liver cancer.

311. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H_2 blockers.[144] These cancers include breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.[145]

C. DEFENDANTS' KNOWLEDGE OF THE NDMA RISK

312. As early as 1981, two years before Zantac entered the market, research showed

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[142] Kim Tu Tran et al., *Proton Pump Inhibitor and Histamine-2 receptor Antagonist Use and Risk of Liver Cancer in Two Population-based Studies*, 48 Alimentary Pharmacology & Therapeutics 1, 55-64 (2018).

[143] Y-H J Shao et al., *Association Between Proton Pump Inhibitors and the Risk of Hepatocellular Carcinoma*, 48 Alimentary Pharmacology & Therapeutics 4, 460-68 (2018).

[144] Mathes et al., *supra* note 140; *see also* Jeong Soo Ahn et al., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 Kuwait Med J. 1, 44-48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503-07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234–38 (2017).

[145] Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines*, The Oncologist, June 2020; 25(6): 460-62, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/.

elevated rates of NDMA, when properly tested.[146] This was known or should have been known Defendants as the information was available in medical literature.

313. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[147] Many metabolites were listed, though there is no indication that the study looked for NDMA.

314. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly found in food and in the body.[148] GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. Manufacturer Defendants knew or should have known about this scientific exchange as it was published in a popular scientific journal. Manufacturer Defendants were obligated to investigate this issue properly. None did.

315. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[149] That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also

[146] *See supra* ¶¶242, 256 (discussing de Flora research).
[147] Carey et al., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed-phase Ion-pair High-performance Liquid Chromatography*, 255 J. Chromatography B: Biomedical Sci. & Appl. 1, 161-68 (1981).
[148] De Flora, *supra* note 92.
[149] Thomas et al., *supra* note 116.

removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987.

316. All Defendants either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or taken action to protect consumers from the NDMA risks in their products. None did.

D. THE FEDERAL REGULATORY LANDSCAPE

317. Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

1. Generic Drugs

318. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed Brand drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its Brand version. In other words, you can take a generic medicine as an equal substitute for its Brand counterpart."[150]

319. While Brand medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA. As the first "A" in ANDA denotes, the generic approval process is "abbreviated" to serve Congress's intent to expeditiously offer

[150] U.S. Food & Drug Admin., *Generic Drugs: Questions & Answers U.S. Food and Drug Administration*, https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers (current as of June 1, 2018)

consumers lower-cost, previously approved medicines. But the abbreviated NDA process does not absolve generic manufacturers of their obligations to ensure that their drugs are safe and effective. To obtain FDA approval, an ANDA applicant must demonstrate that the generic medicine is the same as the Brand version in the following ways:

a. The active ingredient in the generic medicine is the same as in the Brand drug/innovator drug.
b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).
c. The inactive ingredients of the generic medicine are acceptable.
d. The generic medicine is manufactured under the same strict standards as the Brand medicine.
e. The container in which the medicine will be shipped and sold is appropriate.[151]

320. Because the Brand manufacturer previously and theoretically demonstrated clinical safety and efficacy when the NDA was approved, an ANDA applicant does not need to do so if it can show bioequivalence to the branded, reference listed drug ("RLD"). Bioequivalence is the "absence of a significant difference" in the pharmacokinetic profiles of two pharmaceutical products.[152]

321. Though an ANDA applicant's drug must be bioequivalent to the RLD, no two manufacturers' drugs will be exactly the same. For that reason, generic manufacturers are responsible for conducting their *own, independent* stability testing, which must be "designed to assess the stability characteristics of drug products."[153]

322. Because a generic manufacturer's drug must be bioequivalent to the RLD, a compliant generic label should be "the same as the labeling of the reference listed drug" in many

[151] U.S. Food & Drug Admin., *Generic Drug Facts*, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts (current as of June 1, 2018).
[152] 21 C.F.R. §§320.1(e) & 314.3(b).
[153] *Id.*, §211.166(a).

respects.[154] But, because a generic drug may not be exactly the same as the RLD, the generic label "may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance."[155] This regulation by its terms does not apply to non-label elements of a generic drug, including the container and number of units.

323. Pursuant to this regulation, it is common for a generic drug's label to differ from the RLD by setting a different expiration date, requiring the drug to be shipped and stored under different temperature conditions, and/or requiring the drug to receive different (or no) exposure to light. Several of the Generic Prescription Manufacturer Defendants relied on 21 C.F.R. §314.94(a)(8)(iv) and their independent stability studies to sell approved, generic ranitidine with labels that differed from the RLD label.

2. Federal Law Required the Manufacturer Defendants to Notify the FDA about the Presence of NDMA in Ranitidine-Containing Products

324. During the time that Defendants manufactured and sold Ranitidine-Containing Products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. Manufacturer Defendants failed to report these risks to the FDA.

325. Manufacturer Defendants concealed the ranitidine–NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

326. Manufacturers (brand and generic) of an approved drug are required by regulation

[154] *Id.*, §314.94(a)(8)(iii).
[155] *Id.*, §314.94(a)(8)(iv).

to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. §314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

327. Title 21 C.F.R. §314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

328. Manufacturer Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine-Containing Products.

329. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

330. Manufacturer Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the various ways that ranitidine transforms into NDMA. Accordingly, because Manufacturer Defendants never properly disclosed the risks to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any

proposed warning or proposal for transport / storage.

331. When the FDA eventually learned about the NDMA risks posed by Ranitidine-Containing Products, it ordered manufacturers to voluntarily remove the products from the market. Thus, had any Manufacturer Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove Ranitidine-Containing Products from the market.

3. Good Manufacturing Practices as Applicable to All Defendants, Including the Store-Brand Defendants' Obligations

332. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[156]

333. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

334. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine.

335. Based on the above, the Defendants, including the Store-Brand Defendants, had a

[156] 21 U.S.C. §351(a)(2)(B).

duty and was obligated to ensure that its ranitidine was properly stored, handled, and warehoused by it and its suppliers.

336. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.[157] FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling.

337. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And, while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

338. Nothing prevented any Defendant, including the Store-Brand Defendants, from, on their own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring that ranitidine was not exposed to heat or moisture over long periods and by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented the Store-Brand Defendants from ensuring that ranitidine was not exposed to humidity or moisture.

339. Based on the public scientific information, Defendants, including the Store-Brand Defendants, knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

[157] Woodcock Letter, *supra* note 95.

340. At no time did Defendants, including the Store-Brand Defendants, change the labelling of Ranitidine-Containing Products to shorten the expiration date. The Store-Brand Defendants had the ability to cause its suppliers to unilaterally make such label changes for Ranitidine-Containing Products without prior FDA approval pursuant to the CBE regulation. Had the Store-Brand Defendants attempted such label changes, the FDA would not have rejected them.

341. Because the Store-Brand Defendants failed to include appropriate expiration dates on its products, they failed to warn regarding and made false statements in the labeling of its products.

342. Further, as alleged above, each Private Label Distributor was required to conduct, or cause its contract manufacturer to conduct, stability testing, which was required to take the container into account.

343. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

344. Defendants, including the Store-Brand Defendants knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

345. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

346. A substantial factor in NDMA formation was the container system the Store-Brand Defendants chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

347. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

348. The Store-Brand Defendants could have changed, or caused its contract manufacturers to change, the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes Being Effected regulation.

349. FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes Being Effected regulation.

350. The Store-Brand Defendants was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.

351. A reasonably prudent private label distributor would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

352. As an example only, Walmart sold its Equate ranitidine product in bottles with as many as 220 tablets. Similarly, Walgreens sold its Wal-Zan ranitidine products in bottles with as many as 200 tablets. CVS also sold its ranitidine products, called CVS Health, in bottles with as many as 200 tablets.

353. Further the demand for large quantity package sizes put Defendants, including

Store-Brand Defendants, on notice that purchases were made for regular and extended use, and not for a one-time occasion.

354. Because the Store-Brand Defendants failed to package its products in appropriate container sizes, those Defendants failed to warn regarding and made false statements in the packaging of its products.

355. During the time that the Defendants repackaged, distributed, and sold Ranitidine-Containing Products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA.

356. The U.S. Pharmacopeia Convention (hereinafter "USP") sets forth industry standards applicable – in relevant part – to distributors. Chapter 1079, entitled "Good Storage and Shipping Practices," specifies that:

> Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the following: . . .
>
> - Repackaging operations in which the drug product may be owned by an organization other than the primary manufacturer
> - Pharmacies including but not limited to retail, compounding, specialty, mail order, hospital, and nursing home pharmacies. . .
> - Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services.

357. USP 1079 further states that the

> drug product manufacturer (in the case of many OTSs, where there is no application) and the repackager bear primary responsibility and accountability including but not limited to the following: . . .
>
> - Determining proper storage and handling practices
> - Communicating storage and distribution practices through the supply chain
> - Drug product stability profiles or the associated stability information from the holder, inclusive of distribution conditions and excursion that may be allowable should they occur. These stability profiles include the approved storage conditions for the shelf life of the drug product and, where

> applicable, supporting data for the distribution conditions, if they differ from the storage conditions.

358. USP 1079 continues: "However, all organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the drug product identity, strength, quality, purity, or safety."

359. Store-Brand Defendants conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. The Store-Brand Defendants made conscious decisions not to change the containers for its Ranitidine-Containing Products.

E. DEFENDANTS' TORTIOUS CONDUCT IN PACKAGING AND LABELING

1. Brand Prescription Manufacturer GSK's Failure to Warn and Misrepresentations in the Labeling of Ranitidine-Containing Products

360. 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) FALSE OR MISLEADING LABEL
>
> (1) If its labeling is false or misleading in any particular.

361. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[158] and conform to requirements governing the appearance of the label.[159]

362. "Labeling" encompasses all written, printed, or graphic material accompanying the drug or device,[160] and, therefore, broadly encompasses nearly every form of promotional activity,

[158] 21 C.F.R. §201.5.
[159] *Id.* §201.15.
[160] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).

including not only "package inserts" but also advertising.

363. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[161]

364. GSK was responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[162] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[163]

365. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[164] And, expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[165] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."[166]

366. Notably, while generic medications must have the same active ingredients as their branded counterparts, the inactive ingredients, or excipients, may not necessarily be identical. For

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[161] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[162] 21 C.F.R. §211.166(a).
[163] *Id.*
[164] *Id.*
[165] *Id.*, §211.137(a).
[166] *Id.*, §211.137(b).

this reason, the stability of each generic drug may differ from manufacturer to manufacturer, or even from manufacturing process to manufacturing process.

367. GSK was required to conduct its own tests to determine and set accurate retest or expiration dates.

368. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[167]

369. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[168]

370. After a drug is approved, a manufacturer (brand or generic) can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§314.70 and 314.71.[169]

371. Some of the requirements in those regulations require a brand or generic

[167] 43 Fed. Reg. 45059 (Sept. 29, 1978).
[168] 21 C.F.R. §211.166(b).
[169] *See id.*, §314.97(a) (requiring generics to comply with §§314.70, 314.71).

manufacturer of an approved drug to obtain FDA approval before implementing a label change.[170]

372. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[171]

373. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[172] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[173]

374. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date – which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[174] – or to ensure that the drug is shipped and stored under appropriate conditions.

375. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under §201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or

[170] *Id.*, §314.70(b).
[171] *Id.*, §314.70(c)(3), (c)(6).
[172] *Id.*, §314.70(c)(6)(i).
[173] 65 Fed. Reg. 83042 (Dec. 29, 2000).
[174] 21 C.F.R. §211.137(a).

claims for effectiveness."[175]

376. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[176]

377. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."[177]

378. At no time did GSK attempt to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; and (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

379. At no time did GSK attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

380. Based on the public scientific information, GSK knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

[175] *Id.*, §314.70(c)(6)(iii)(A), (C), (D).
[176] *Id.*, §314.70 (d)(2)(ix).
[177] *Id.*, §314.70 (d)(2)(vi); *see also id.*, §314.70(d)(2)(vii), (x).

381. At no time did GSK change its label to shorten the expiration date. GSK had the ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Manufacturer Defendant attempted such label changes, the FDA would not have rejected them.

382. Because they failed to include appropriate expiration dates on their products, Manufacturer Defendants made failed to warn regarding and made false statements in the labeling of their products.

383. Because it failed to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; and (iv) consumed daily for a period of greater than a few months, GSK failed to warn regarding and made false statements in the labeling of its products.

2. The Brand OTC Manufacturer Defendants' Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

384. The Brand OTC Manufacturer Defendants are GSK, Pfizer, BI, and Sanofi.

385. Each of these Brand OTC Manufacturer Defendants increased OTC Ranitidine–Containing Product demand through a fundamental and uniform message, parlayed through a multi-media campaign that OTC Zantac is safe, it can be used frequently, long-term, with high-nitrate and -nitrite foods, and poses no serious health risks such as those associated with the consumption of NDMA—a known human carcinogen.

386. Examples of this campaign include a series of television, print, radio, and internet ads for OTC Zantac throughout the United States and to consumers that uniformly omitted the material safety risks that the products contained NDMA, that ranitidine was instable, that NDMA

content could increase through the lapse of time and when exposed to heat or humidity, and that it should not be used in connection with high-nitrate or -nitrite foods.

387. At the point of sale, Brand OTC Manufacturer Defendants sold Zantac packaged and labeled with misleading information and material omissions.

a. Failure to Warn and Misrepresentations with Respect to the Labels

388. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) False or misleading label
>
> (1) If its labeling is false or misleading in any particular.

389. The Brand OTC Manufacturer Defendants were required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended," and conform to requirements governing the appearance of the label.

390. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, and, therefore, broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

391. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."

392. The Brand OTC Manufacturer Defendants were also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products." Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of

stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."

393. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates." And, expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use." An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."

394. Each Brand OTC Manufacturer Defendant must conduct its own tests to determine and set accurate retest or expiration dates.

395. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."

396. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."

397. After a drug is approved, a brand manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§314.70 and 314.71.

398. Some of the requirements in those regulations require a brand manufacturer of an approved drug to obtain FDA approval before implementing a label change.

399. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.

400. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess." "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."

401. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date – which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"—or to ensure that the drug is shipped and stored under appropriate conditions.

402. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under §201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."

403. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."

404. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."

405. At no time did any Brand OTC Manufacturer Defendant attempt to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; and (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

406. At no time did any Brand OTC Manufacturer Defendant attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

407. Based on the public scientific information, the any Brand OTC Manufacturer Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

408. At no time did any Brand OTC Manufacturer Defendant change its label to shorten the expiration date. Brand OTC Manufacturer Defendants had the ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Brand OTC Manufacturer Defendant attempted such label changes, the FDA

would not have rejected them.

409. Because they failed to include appropriate expiration dates on their products, Brand OTC Manufacturer Defendants failed to warn regarding and made false statements in the labeling of their products.

410. Because they failed to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods;and (iv) consumed daily for a period of greater than a few months, Brand OTC Manufacturer Defendants failed to warn regarding and made false statements in the labeling of their products.

b. Failure to Warn and Misrepresentations with Respect to the Packaging

411. 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded—
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**
>
> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;

(emphasis in original).

412. As alleged above, each Brand OTC Manufacturer Defendant was required to conduct stability testing, which was required to take the container into account.

413. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

414. The Brand OTC Manufacturer Defendants knew that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

415. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

416. A substantial factor in NDMA formation was the container system manufacturers chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

417. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

418. Each Brand OTC Manufacturer Defendant could have unilaterally changed the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation. *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (*e.g.*, tablets, capsules) or labeled amount (*e.g.*, grams, milliliters) of a nonsterile drug product in a unit-of-use container."). FDA guidance also would treat changing to a unit-dose container such as a blister-

pack to be a moderate change that could be implemented through the Changes-Being Effected regulation. *See id.* at 20-21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

419. Brand OTC Manufacturer Defendants were not required to put their ranitidine in the same containers as the others, because the duty of sameness does not apply to containers. It applies only to the drug label. *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

420. A reasonably prudent manufacturer would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

421. As examples only, beginning in or about December 2006, BI sold Zantac 75 mg under NDC 0597-0122-96 in a bottle containing 96 pills, under NDC 0597-0122-81 in a bottle containing 80 pills, and under NDC 0597-0122-61 in a container containing 100 pills in pouches.

422. As examples only, beginning in or about December 2006, BI sold Zantac Maximum Strength 150 Cool Mint under NDC 0597-0120-87 in a bottle containing 85 tablets, under NDC 0597-0120-82 in a container containing 80 tablets in pouches, and under NDC 0597-0120-78 in a bottle containing 78 tablets.

423. An example of a BI label for a package of 80 tablets follows:

424. As examples only, beginning in or about April 2018, Sanofi sold Zantac 150 mg under NDC 41167-0310-6 in a bottle containing 90 tablets, under NDC 41167-0310-9 in a bottle containing 78 pills, and under 41167-0310-8 in two bottles packaged in one carton with each bottle

containing 60 tablets (for a 120-tablet package).

425. An example of a Sanofi label for a package of 90 tablets follows:

426. Because they failed to package their products in appropriate container sizes, Brand

OTC Manufacturer Defendants failed to warn regarding and made false statements with regard to the packaging of their products.

427. Brand OTC Manufacturer Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Brand OTC Manufacturer Defendants have made conscious decisions not to change the containers for their Ranitidine-Containing Products.

3. Generic Prescription Manufacturer Defendants' Failure to Warn and Misrepresentations in the Labeling of Prescription Ranitidine-Containing Products

428. The Generic Prescription Manufacturer Defendants are Amneal, Apotex, Dr. Reddy's, Glenmark, Sandoz, Strides, and Teva.

429. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

430. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended," and conform to requirements governing the appearance of the label.

431. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, and, therefore, broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

432. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude

from the definition printed matter which constitutes advertising."

433. All drug manufacturers (brand and generic) are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products." Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."

434. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates." And, expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use." An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."

435. Notably, while generic medications must have the same active ingredients as their branded counterparts, the inactive ingredients, or excipients, may not necessarily be identical. For this reason, the stability of each generic drug may differ from manufacturer to manufacturer, or even from manufacturing process to manufacturing process.

436. Each generic manufacturer must therefore conduct its own tests to determine and set accurate retest or expiration dates.

437. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for

multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."

438. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."

439. After a drug is approved, a generic manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§314.70 and 314.71.

440. Some of the requirements in those regulations require the manufacturer of an approved drug to obtain FDA approval before implementing a label change.

441. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.

442. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess." "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."

443. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date – which must "assure that a drug product

meets applicable standards of identity, strength, quality, and purity at the time of use" – or to ensure that the drug is shipped and stored under appropriate conditions.

444. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under §201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."

445. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."

446. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."

447. At no time did any Generic Manufacturer Defendant attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

448. Based on the public scientific information, the Generic Manufacturer Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

449. At no time did any Generic Manufacturer Defendant change its label to shorten the expiration date. The Generic Manufacturer Defendants had the ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Generic Manufacturer Defendant attempted such label changes, the FDA would not have rejected them.

450. Because they failed to include appropriate expiration dates on their products, the Generic Manufacturer Defendants failed to warn regarding and made false statements in the labeling of their products.

4. The Store-Brand Defendants' Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

451. The Store-Brand Defendants (or Private-Label Distributors, ("PLDs"))[178] are Walmart, Walgreens, CVS, and Rite Aid.

452. The FDA considers a firm that does not manufacture or process the drug but instead markets and distributes it under its own trade name, and labels a drug product made by someone else, a PLD.

453. While a PLD contracts with a contract manufacturing organization ("CMO") to manufacture and process a drug, the FDA holds the PLD responsible for ensuring that all of its products comply with cGMPs, are not adulterated for failure to comply with cGMPs, and are not misbranded.

454. Delegating manufacturing or testing operations for a store-branded product to other companies does not exonerate the PLD from complying with its regulatory and state law requirements.

[178] Defined at 21 C.F.R. §207.1.

455. Thus, a PLD that contracts out some or all of its operations must establish a system of production and process controls to ensure its private-label product is not adulterated or misbranded prior to distribution or sale.

a. CVS' Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. CVS is a Private Label Distributor for the Private-Label Product CVS Health Ranitidine

456. CVS offers store brands, which are low-priced alternatives to name-brand products. CVS has numerous store brands, each catering to a different consumer need.

457. Almost all products offered under CVS store-brands are private label products, meaning CVS produces them through subsidized contracts awarded to the lowest bidder.

458. CVS Health is CVS's store brand, or private label, for healthcare needs, including OTC medications.

459. CVS represents that "CVS Health® products meet the highest quality standards for your health, wellness and beauty needs."[179]

460. CVS contracts with third-party manufacturers to manufacture its CVS Health OTC medications.

461. With respect to OTC medications, CVS is considered a PLD. As a PLD, CVS is responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

462. Since at least 1997, CVS has required all suppliers that provide pharmaceutical products to its to abide by its standards and submit to regular audits.

[179] https://www.cvs.com/shopbrand/exclusive-brands?stop_mobi=yes (last accessed Feb. 6, 2021).

463. CVS loftily claims that its "purpose" in helping people on a path to better health means ensuring "a safe working environment" for the "suppliers worldwide."[180]

464. To achieve this goal CVS claims it was the first health care retailer to join the "Responsible Factory Initiative" which is dedicated to corporate social responsibility in global supply chains.

465. This partnership includes training on what CVS purports to be the "most critical risks" in the manufacturing supply chain, including health and safety, chemical management, environmental sustainability, recognizing forced labor, and corrective action planning.

466. CVS proclaims that it maintains the "highest level of performance" in the areas of supply chain responsibility.[181]

467. CVS claims that this high level of performance extends to the "creation and production" of each of CVS's private-label products to ensure the "highest level of quality and environmental safety."[182]

468. CVS touts that its suppliers play an "integral part in our success as a health care leader" and CVS purports to "engage them down to the factor level to better understand the source of our products' raw materials, how and where the products were manufactured, and under what conditions."[183]

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[180] https://cvshealth.com/news-and-insights/articles/strengthening-our-commitment-to-ethical-sourcing-across-our-supply-chain (last accessed Jan. 26, 2021).

[181] https://cvshealth.com/sites/default/files/2018-csr-full-report.pdf (last accessed Jan. 26, 2021).

[182] https://s2.q4cdn.com/447711729/files/doc_downloads/company_documents/2014-CVSCaremark-CSR-Report.pdf (last accessed Feb. 5, 2021)

[183] https://s2.q4cdn.com/447711729/files/doc_downloads/company_documents/2014-CVSCaremark-CSR-Report.pdf (last accessed Feb. 5, 2021)

469. To this end, CVS audits all its suppliers, to ensure that "import suppliers and other store brand suppliers are in compliance with social, legal and trade security standards" in manufacturing OTC products for consumers.[184]

470. CVS requires all suppliers to submit to "Intertek GMP quality audits" to "be performed on all factories producing Store Brand FDA regulated items."[185]

471. In or about 2012, CVS launched "an enhanced factory audit program" with an aim "to help ensure our import suppliers and global supply chain partners" comply with "good manufacturing processes". As CVS explained in a training for suppliers:[186]

472. To that end, CVS stated in its training that any supplier of a private-label product that was both a "CVS Store Brand Import Item" and "FDA Regulated Import Item" was required

[184] https://s2.q4cdn.com/447711729/files/doc_downloads/company_documents/2014-CVSCaremark-CSR-Report.pdf (last accessed Feb. 5, 2021).

[185] https://www.cvssuppliers.com/sites/default/files/Direct%20Import%20Guide%20For%20Product%20Suppliers%20063017_.pdf (last accessed Feb. 6, 2021).

[186] https://studylib.net/doc/8860947/cvs-factory-audit-program (last accessed Feb. 6, 2021).

to submit to four types of audits: WCA, GSV, GMP, and SQP.[187] Likewise, any supplier of a private-label product that was both a "CVS Store Domestic Purchased Item" and "FDA Regulated Domestic Purchased Item" was required to submit to two types of audits: GMP and SQP.[188]

473. These acronyms stand for: Workplace Conditions Audit/Social Audit (WCA); Global Security Verification/Security Audit (GSV); Supplier Qualification Program/Quality Audit (SQP); and Good Manufacturing Practices/ Quality Audit for Regulated Items (GMP).[189]

474. CVS's supplier requirements demonstrate its knowledge that it is ultimately responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

475. As part of its CVS Health OTC product line, CVS sold ranitidine.

476. An example of a CVS Health label for CVS's store-brand or private-label ranitidine follows:[190]

[187] *Id.*

[188] *Id.*

[189] *Id.*

[190] https://www.instacart.com/products/2679999-cvs-health-acid-reducer-regular-strength-75-mg-tablets-80-ea (last accessed Feb. 6, 2021).

477. CVS's ranitidine products can be identified by the unique labeler code assigned to CVS by the FDA: 69842. Any NDC number starting with 69842 is a CVS private-label product.

478. A list of the CVS Health ranitidine products sold by CVS as the PLD includes, *inter alia:*

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
CVS Health Ranitidine (CVS)						
	150 mg	95 tablet bottle	69842-869-62	ANDA078192	Dr. Reddys	5/1/2010
	75 mg	30 tablet bottle	69842-871-30	ANDA075294	Dr. Reddys	7/1/2009
	75 mg	160 tablet bottle	69842-871-37	ANDA075294	Dr. Reddys	7/1/2009
	75 mg	80 tablet bottle	69842-871-80	ANDA075294	Dr. Reddys	7/1/2009
	75 mg	160 tablet bottle	69842-293-06	ANDA076195	Perrigo	5/25/2018
	75 mg	80 tablet bottle	69842-293-27	ANDA076195	Perrigo	5/25/2018
	75 mg	30 tablet bottle	69842-293-65	ANDA076195	Perrigo	5/25/2018
	150 mg	95 tablet bottle	59779-540-01	ANDA091429	Perrigo	9/14/2015
	150 mg	24 tablet bottle	59779-540-02	ANDA091429	Perrigo	9/14/2015
	150 mg	65 tablet bottle	59779-540-09	ANDA091429	Perrigo	9/14/2015
	150 mg	200 tablet bottle	59779-540-82	ANDA091429	Perrigo	9/14/2015
	150 mg	95 tablet bottle	59779-950-01	ANDA091429	Perrigo	9/21/2011
	150 mg	65 tablet bottle	59779-950-09	ANDA091429	Perrigo	9/21/2011
	150 mg	1 tablet in blister pack, 8 blister pack	59779-950-51	ANDA091429	Perrigo	9/21/2011
	150 mg	1 tablet in blister pack, 24 blister pack	59779-950-62	ANDA091429	Perrigo	9/21/2011
	150 mg	32 tablet bottle	59779-950-64	ANDA091429	Perrigo	9/21/2011
	75 mg	80 tablet bottle	59779-356-08	ANDA201745	Strides	9/9/2013
	75 mg	160 tablet bottle	59779-356-16	ANDA201745	Strides	9/9/2013
	75 mg	30 tablet blister pack	59779-356-31	ANDA201745	Strides	9/9/2013
	150 mg	200 tablet bottle	59779-354-20	ANDA200536	Strides	8/21/2012
	150 mg	24 tablet blister pack	59779-354-24	ANDA200536	Strides	8/21/2012
	150 mg	65 tablet bottle	59779-354-65	ANDA200536	Strides	8/21/2012
	150 mg	95 tablet bottle	59779-354-95	ANDA200536	Strides	8/21/2012

479. CVS contracted with Perrigo, Dr. Reddy's Laboratories, and Strides to manufacture its CVS Health ranitidine products.

480. Delegating manufacturing or testing operations for CVS Health ranitidine to other

companies did not exonerate CVS as the PLD from its regulatory requirements to establish a system of production and process controls to ensure its private-label products were not adulterated or misbranded prior to sale.

ii. CVS' Failure to Warn and Misrepresentations with Respect to the Labels

481. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

482. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

483. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, CVS had a duty and was obligated to properly store, handle, and warehouse ranitidine.

484. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[191] The FDA has also concluded that NDMA can

[191] Woodcock Letter, *supra* note 95.

increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

485. Nothing prevented CVS from, on its own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented CVS from ensuring that ranitidine was not exposed to humidity or moisture.

486. At no time did CVS attempt to include, or cause its suppliers to attempt to include, a warning on the labels for CVS Health ranitidine that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

487. At no time did CVS attempt to change, or cause its suppliers to attempt to change, the CVS Health ranitidine label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that CVS Health ranitidine products would not break down into NDMA prior to human consumption.

488. An example of a CVS Health ranitidine label reflecting that expiration dates were included on the packaging follows:

489. Based on the public scientific information, CVS knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

490. At no time did CVS change its CVS Health ranitidine label to shorten the expiration date. CVS had the ability to cause its suppliers to unilaterally make such label changes for CVS Health ranitidine without prior FDA approval pursuant to the CBE regulation. Had CVS attempted such label changes, the FDA would not have rejected them.

491. Because CVS failed to include appropriate expiration dates on its products, CVS failed to warn regarding and made false statements in the labeling of its products.

iii. CVS' Failure to Warn and Misrepresentations with Respect to the Packaging

492. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**

> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

493. As alleged above, each PLD was required to conduct, or cause its contract manufacturer to conduct, stability testing, which was required to take the container into account.

494. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

495. CVS knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

496. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

497. A substantial factor in NDMA formation was the container system CVS chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

498. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

499. CVS could have changed, or caused its contract manufacturers to change, the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[192] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[193]

500. CVS was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[194]

501. A reasonably prudent PLD would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

502. As reflected in the chart above, and as an example only, CVS sold its CVS Health ranitidine product in bottles with as many as 200 tablets.

503. A copy of the label for the CVS Health ranitidine product with 200 tablets follows:

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[192] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (*e.g.*, grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[193] *See id.* at 20-21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

[194] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

504. Further the demand for large quantity package sizes put CVS on notice that purchases were made for regular and extended use, and not for a one-time occasion.

505. Because CVS failed to package its products in appropriate container sizes, CVS failed to warn regarding and made false statements in the packaging of its products.

506. CVS's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. CVS made conscious decisions not to change the containers for its Ranitidine-Containing Products.

b. Rite Aid's Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Rite Aid Is a Private Label Distributor for the Private-Label Product Rite Aid Ranitidine

507. Rite Aid offers store brands, which are low-priced alternatives to name-brand products. Rite Aid has numerous store brands, each catering to a different consumer need.

508. Almost all products offered under Rite Aid store-brands are private label products, meaning Rite Aid produces them through subsidized contracts awarded to the lowest bidder.

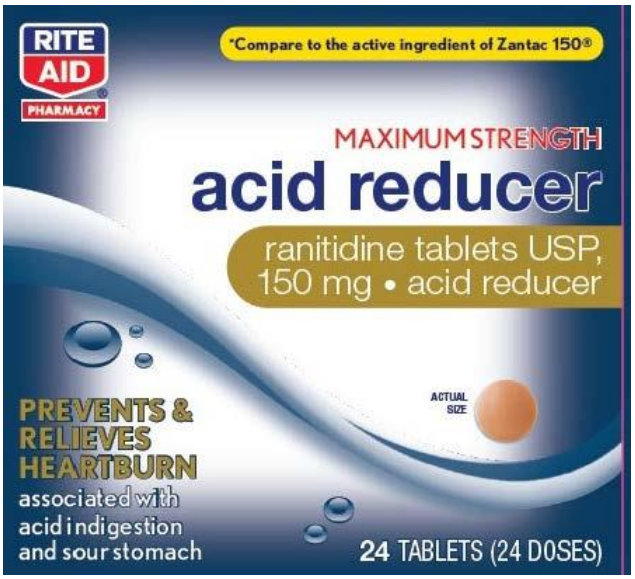
509. Rite Aid is Rite Aid's store brand, or private label, for, *inter alia,* OTC medications.

510. Rite Aid contracts with third-party manufacturers to manufacture its Rite Aid OTC medications.

511. With respect to OTC medications, Rite Aid is considered a PLD. As a PLD, Rite Aid is responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

512. As part of its Rite Aid OTC product line, Rite Aid sold ranitidine.

513. An example of a Rite Aid acid reducer ranitidine label for Rite Aid's store-brand or private-label ranitidine follows:



514. Rite Aid's ranitidine products can be identified by the unique labeler code assigned to Rite Aid by the FDA: 11822. Any NDC number starting with 11822 is a Rite Aid private-label

product.

515. A list of the Rite Aid ranitidine products sold by Rite Aid as the PLD includes, *inter alia:*

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Rite Aid Ranitidine						
	150 mg	1 tablet in 1 blister pack, 24 blister pack	11822-0852-1	ANDA091429	Perrigo	10/26/2011
	150 mg	50 tablet bottle	11822-0852-2	ANDA091429	Perrigo	10/26/2011
	150 mg	65 tablet botlte	11822-0852-3	ANDA091429	Perrigo	10/26/2011
	150 mg	95 tablet bottle	11822-0852-4	ANDA091429	Perrigo	10/26/2011
	150 mg	24 tablet bottle	11822-0852-5	ANDA091429	Perrigo	10/26/2011
	150 mg	24 tablet bottle	11822-0950-0	ANDA091429	Perrigo	12/7/2011
	150 mg	50 tablet bottle	11822-0950-1	ANDA091429	Perrigo	12/7/2011
	150 mg	95 tablet bottle	11822-4727-3	ANDA200172	Apotex	6/26/2017
	150 mg	24 tablet bottle	11822-6051-8	ANDA200172	Apotex	6/26/2017
	150 mg	50 tablet bottle	11822-6052-1	ANDA200172	Apotex	6/26/2017
	150 mg	65 tablet bottle	11822-6052-2	ANDA200172	Apotex	6/26/2017
	150 mg	24 tablet bottle	11822-6107-4	ANDA200172	Apotex	6/30/2017
	75 mg	30 tablet bottle	11822-6190-0	ANDA200536	Strides	6/15/2013
	75 mg	60 tablet bottle	11822-6190-1	ANDA200536	Strides	6/15/2013
	75 mg	80 tablet bottle	11822-6190-8	ANDA200536	Strides	6/15/2013
	150 mg	24 blister pack	11822-0852-1	ANDA091429	Perrigo	10/26/2011
	150 mg	50 tablet bottle	11822-0852-2	ANDA091429	Perrigo	10/26/2011
	150 mg	65 tablet bottle	11822-0852-3	ANDA091429	Perrigo	10/26/2011
	150 mg	95 tablet bottle	11822-0852-4	ANDA091429	Perrigo	10/26/2011
	150 mg	24 tablet bottle	11822-0852-5	ANDA091429	Perrigo	10/26/2011
	75 mg	60 tablet bottle	11822-0271-1	ANDA076760	Wockhardt	11/4/2011
	75 mg	2 bottle carton, 80 tablets per bottle	11822-0271-2	ANDA076760	Wockhardt	11/4/2011
	75 mg	30 tablet bottle	11822-0271-3	ANDA076760	Wockhardt	11/4/2011
	150 mg	50 tablet bottle	11822-0047-1	ANDA078653	Wockhardt	12/3/2008
	150 mg	24 tablet blister pack	11822-0047-2	ANDA078653	Wockhardt	12/3/2008
	150 mg	65 tablet bottle	11822-0047-3	ANDA078653	Wockhardt	12/3/2008
	150 mg	95 tablet bottle	11822-0047-4	ANDA078653	Wockhardt	12/3/2008

516. Rite Aid contracted with Perrigo, Apotex, and Strides, and non-party Wockhardt, to manufacture its Rite Aid ranitidine products.

517. Delegating manufacturing or testing operations for Rite Aid ranitidine products to other companies did not exonerate Rite Aid as the PLD from its regulatory requirements to establish a system of production and process controls to ensure its private-label products were not adulterated or misbranded prior to sale.

ii. Rite Aid's Failure to Warn and Misrepresentations with Respect to the Labels

518. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

519. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

520. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Rite Aid had a duty and was obligated to properly store, handle, and warehouse ranitidine.

521. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[195] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

522. Nothing prevented Rite Aid from, on its own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Rite Aid from ensuring that ranitidine was not exposed to humidity or moisture.

523. At no time did Rite Aid attempt to include, or cause its suppliers to attempt to include, a warning on the labels for Rite Aid ranitidine that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

524. At no time did Rite Aid attempt to change, or cause its suppliers to attempt to change, the Rite Aid ranitidine label to delete a false or misleading expiration date, or to add a

[195] Woodcock Letter, *supra* note 95.

proper expiration date to ensure that Rite Aid ranitidine products would not break down into NDMA prior to human consumption.

525. An example of a Rite Aid ranitidine label reflecting that expiration dates were included on the packaging follows:[196]

526. Based on the public scientific information, Rite Aid knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

527. At no time did Rite Aid change its Rite Aid ranitidine label to shorten the expiration date. Rite Aid had the ability to cause its suppliers to unilaterally make such label changes for

[196] https://ndclist.com/ndc/11822-0950.

Rite Aid ranitidine without prior FDA approval pursuant to the CBE regulation. Had Rite Aid attempted such label changes, the FDA would not have rejected them.

528. Because Rite Aid failed to include appropriate expiration dates on its products, Rite Aid failed to warn regarding and made false statements in the labeling of its products.

iii. Rite Aid's Failure to Warn and Misrepresentations with Respect to the Packaging

529. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**
>
> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

530. As alleged above, each PLD was required to conduct, or cause its contract manufacturer to conduct, stability testing, which was required to take the container into account.

531. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

532. Rite Aid knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

533. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

534. A substantial factor in NDMA formation was the container system Rite Aid chose.

Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

535. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

536. Rite Aid could have changed, or caused its contract manufacturers to change, the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[197] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[198]

537. Rite Aid was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[199]

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[197] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[198] *See id.* at 20-21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

[199] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

538. A reasonably prudent PLD would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

539. As reflected in the chart above, and as an example only, Rite Aid sold its CVS Health ranitidine product in bottles with as many as 95 tablets.

540. A copy of the label for the Rite Aid ranitidine product with 95 tablets follows:

541. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

542. Because Rite Aid failed to package its products in appropriate container sizes, Rite Aid failed to warn regarding and made false statements in the packaging of its products.

543. Rite Aid's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Rite Aid made conscious decisions not to change the containers for its

Ranitidine-Containing Products.

c. Walgreens' Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Walgreens is a Private Label Distributor for the Private-Label Product Wal-Zan Ranitidine

544. Walgreens offers store brands, which are low-priced alternatives to name-brand products. Walgreens has numerous store brands, each catering to a different consumer need.

545. Almost all products offered under Walgreens store-brands are private label products, meaning Walgreens produces them through subsidized contracts awarded to the lowest bidder.

546. Walgreens uses the pre-fix "Wal-" together with a portion of the brand-name of an OTC medication to name its private-label OTC products. For example, Wal-Flu is Walgreens' private-label product that competes with Theraflu, Wal-itin is Walgreens' private label product that competes with Claritin, and Wal-Dryl is Walgreens' private-label product that is comparable to Benadryl.

547. Walgreens contracts with third-party manufacturers to manufacture its "Wal-" OTC medications.

548. With respect to OTC medications, Walgreens is considered a PLD. As a PLD, Walgreens is responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

549. Walgreens states that it understands that consumers "want to feel confident the products they use are safe for their intended purposes."[200]

[200] https://www.walgreens.com/topic/sr/sr_product_integrity_home.jsp (last accessed Jan. 26, 2021).

550. Walgreens claims it aims to do "business fairly and with integrity" which has led Walgreens to "drive responsible sourcing practices throughout our supply chain, protecting human rights and engaging with suppliers around ethical and environmental issues."[201]

551. According to Walgreens, "[p]atient safety lies at the heart of our management of pharmacy operations, and we strive to be the industry leader by continuously seeking ways to minimize risks to patients in our dispensing, pharmacy services and advance and pharmacy supply chain operations."[202]

552. Walgreens claims it engages in "ongoing supplier ethical compliance assessments" which includes "engaging with suppliers to improve when issues are detected."

553. Walgreens also claims to screen suppliers against a matrix which assesses the suppliers' management systems to discern whether they are operating in any way which violates Walgreens' ethical sourcing commitments.[203]

554. Walgreens' supplier requirements demonstrate its knowledge that it is ultimately responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

555. As part of its "Wal-" OTC product line, Walgreens sold ranitidine labeled "Wal-Zan," which was intended to compete with brand-name Zantac OTC products.

556. An example of a Wal-Zan label for Walgreens' store-brand or private-label

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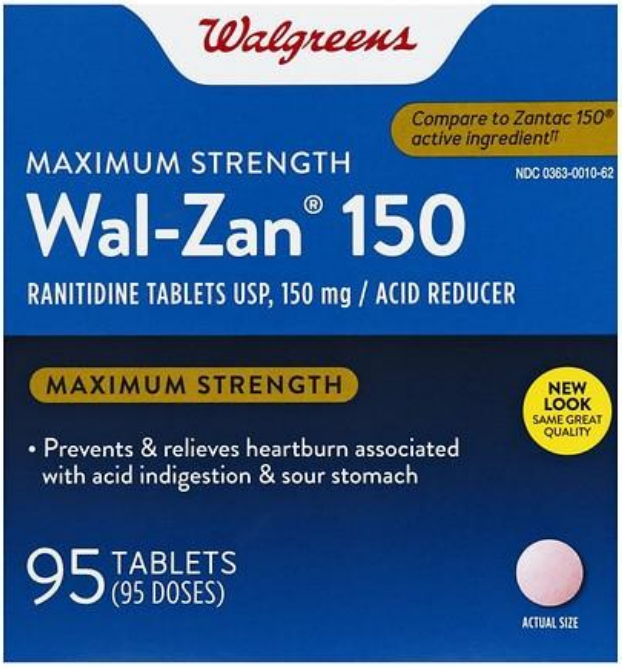
[201] https://www.walgreensbootsalliance.com/sites/www/files/asset/Walgreens-Boots-Alliance-2019-Corporate-Social-Responsibility-Report_2.pdf (last accessed Jan. 26, 2021).

[202] https://www.walgreensbootsalliance.com/sites/www/files/asset/Walgreens-Boots-Alliance-2019-Corporate-Social-Responsibility-Report_2.pdf (last accessed Jan. 26, 2021).

[203] https://www.walgreensbootsalliance.com/sites/www/files/asset/Walgreens-Boots-Alliance-2019-Corporate-Social-Responsibility-Report_2.pdf (last accessed Jan. 26, 2021).

ranitidine follows:[204]



557. Walgreens Wal-Zan ranitidine products can be identified by the unique labeler code assigned to Walgreens by the FDA: 0363. Any NDC number starting with 0363 is a Walgreens private-label product.

558. A list of the Wal-Zan ranitidine products sold by Walgreens as the PLD includes, *inter alia*:

[204] https://www.upcitemdb.com/upc/311917126432 (last accessed Feb. 6, 2021).

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Wal-Zan Ranitidine						
	150 mg	200 tablet bottle	0363-0010-01	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	36 tablet bottle	0363-0010-23	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	65 tablet bottle	0363-0010-26	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	32 tablet bottle	0363-0010-32	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	24 tablet bottle	0363-0010-34	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	50 tablet bottle	0363-0010-50	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	65 tablet bottle	0363-0010-61	ANDA078192	Dr. Reddys	6/11/2011
	75 mg	30 tablet bottle	0363-0131-30	ANDA075294	Dr. Reddys	1/6/2014
	75 mg	45 tablet bottle	0363-0131-33	ANDA075294	Dr. Reddys	1/6/2014
	75 mg	80 tablet bottle	0363-0131-80	ANDA075294	Dr. Reddys	1/6/2014
	150 mg	65 tablet bottle	0363-1030-01	ANDA200172	Apotex	7/31/2015
	150 mg	24 tablet bottle	0363-1030-02	ANDA200172	Apotex	7/31/2015
	150 mg	50 tablet bottle	0363-1030-05	ANDA200172	Apotex	7/31/2015
	150 mg	65 tablet bottle	0363-1030-06	ANDA200172	Apotex	7/31/2015
	150 mg	200 tablet bottle	0363-1030-07	ANDA200172	Apotex	7/31/2015
	150 mg	95 tablet bottle	0363-1030-09	ANDA200172	Apotex	7/31/2015
	150 mg	95 tablet bottle	0363-0852-01	ANDA091429	Perrigo	1/11/2019
	150 mg	65 tablet bottle	0363-0852-09	ANDA091429	Perrigo	1/11/2019
	150 mg	1 tablet in 1 blister pack, 8 blister pack	0363-0852-51	ANDA091429	Perrigo	1/11/2019
	150 mg	1 tablet in 1 blister pack, 24 blister pack	0363-0852-62	ANDA091429	Perrigo	1/11/2019
	150 mg	200 tablet bottle	0363-0852-82	ANDA091429	Perrigo	1/11/2019
	75 mg	80 tablet bottle	0363-0352-08	ANDA201745	Strides	9/24/2013
	75 mg	30 tablet bottle	0363-0352-30	ANDA201745	Strides	9/24/2013
	75 mg	80 tablet bottle	0363-1876-27	ANDA076195	Perrigo	1/11/2019
	75 mg	30 tablet bottle	0363-1876-65	ANDA076195	Perrigo	1/11/2019
	75 mg	80 tablet bottle	0363-1029-08	ANDA075167	Apotex	7/31/2015
	75 mg	80 tablet bottle	0363-0271-27	ANDA076760	Wockhardt	2/24/2009
	75 mg	30 tablet bottle	0363-0271-39	ANDA076760	Wockhardt	2/24/2009
	75 mg	60 tablet bottle	0363-0271-72	ANDA076760	Wockhardt	2/24/2009
	150 mg	24 tablet bottle	0363-0950-02	ANDA091429	Perrigo	9/17/2011
	150 mg	85 tablet bottle	0363-0950-04	ANDA091429	Perrigo	9/17/2011
	150 mg	65 tablet bottle	0363-0950-09	ANDA091429	Perrigo	9/17/2011
	150 mg	32 tablet bottle	0363-0950-64	ANDA091429	Perrigo	9/17/2011
	150 mg	95 tablet bottle	0363-0047-01	ANDA078653	Wockhardt	2/4/2008
	150 mg	24 tablet bottle	0363-0047-02	ANDA078653	Wockhardt	2/4/2008
	150 mg	50 tablet bottle	0363-0047-71	ANDA078653	Wockhardt	2/4/2008
	150 mg	200 tablet bottle	0363-0362-02	ANDA200536	Strides	6/28/2011
	150 mg	24 tablet bottle	0363-0362-23	ANDA200536	Strides	6/28/2011
	150 mg	50 tablet bottle	0363-0362-50	ANDA200536	Strides	6/28/2011
	150 mg	65 tablet bottle	0363-0362-52	ANDA200536	Strides	6/28/2011
	150 mg	95 tablet bottle	0363-0362-95	ANDA200536	Strides	6/28/2011

559. Walgreens contracted with Perrigo, Dr. Reddy's Laboratories, Apotex, Strides, and non-party Wockhardt to manufacture its Wal-Zan ranitidine products.

560. Delegating manufacturing or testing operations for Wal-Zan ranitidine to other companies did not exonerate Walgreens as the PLD from its regulatory requirements to establish a system of production and process controls to ensure its private-label products were not adulterated or misbranded prior to sale.

ii. Walgreens' Failure to Warn and Misrepresentations with Respect to the Labels

561. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

562. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

563. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Walgreens had a duty and was obligated to properly store, handle, and warehouse

ranitidine.

564. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[205] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

565. Nothing prevented Walgreens from, on its own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Walgreens from ensuring that ranitidine was not exposed to humidity or moisture.

566. At no time did Walgreens attempt to include, or cause its suppliers to attempt to include, a warning on the labels for Wal-Zan ranitidine that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

567. At no time did Walgreens attempt to change, or cause its suppliers to attempt to

[205] Woodcock Letter, *supra* note 95.

change, the Wal-Zan ranitidine label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Wal-Zan ranitidine products would not break down into NDMA prior to human consumption.

568. An example of a Wal-Zan ranitidine label reflecting that expiration dates were included on the packaging follows:

569. Based on the public scientific information, Walgreens knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the

human stomach, and/or over time in storage.

570. At no time did Walgreens change its Wal-Zan ranitidine label to shorten the expiration date. Walgreens had the ability to cause its suppliers to unilaterally make such label changes for Wal-Zan ranitidine without prior FDA approval pursuant to the CBE regulation. Had Walgreens attempted such label changes, the FDA would not have rejected them.

571. Because Walgreens failed to include appropriate expiration dates on its products, Walgreens failed to warn regarding and made false statements in the labeling of its products.

iii. Walgreens' Failure to Warn and Misrepresentations with Respect to the Packaging

572. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded—
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**
>
> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

573. As alleged above, each PLD was required to conduct, or cause its contract manufacturer to conduct, stability testing, which was required to take the container into account.

574. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

575. Walgreens knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

576. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of

NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

577. A substantial factor in NDMA formation was the container system Walgreens chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

578. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

579. Walgreens could have changed, or caused its contract manufacturers to change, the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[206] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[207]

580. Walgreens was not required to put its ranitidine in the same containers as the other

[206] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (*e.g.*, grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[207] *See id.* at 20-21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[208]

581. A reasonably prudent PLD would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

582. As reflected in the chart above, and as an example only, Walgreens sold its Wal-Zan ranitidine product in bottles with as many as 200 tablets.

583. A copy of the label for the Wal-Zan ranitidine product with 200 tablets follows:

584. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

[208] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

585. Because Walgreens failed to package its products in appropriate container sizes, Walgreens failed to warn regarding and made false statements in the packaging of its products.

586. Walgreens' conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Walgreens made conscious decisions not to change the containers for its Ranitidine-Containing Products.

d. Walmart's Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Walmart Is a Private Label Distributor for the Private Label Product Equate Ranitidine

587. Walmart offers store brands, which are low-priced alternatives to name-brand products. Walmart has numerous store brands, each catering to a different consumer need.

588. Almost all products offered under Walmart store-brands are private label products, meaning Walmart produces them through subsidized contracts awarded to the lowest bidder.

589. Equate is Walmart's store brand, or private label, for consumable pharmacy and health and beauty items, including OTC medications.

590. Walmart contracts with a third-party manufacturer to manufacture its Equate OTC medications.

591. With respect to OTC medications, Walmart is considered a PLD. As a PLD, Walmart is responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

592. Walmart requires all suppliers that provide prescription pharmaceutical products to its Pharmacy Distribution Centers, either directly or indirectly, to abide by its Responsible

Sourcing Standards for Suppliers.[209]

593. Walmart publishes "Supplier Requirements for Over-the-Counter Drugs, Vitamins, and Dietary & Nutritional Supplements" ("Supplier Requirements").[210]

594. Walmart's Supplier Requirements demonstrate its knowledge that it is ultimately responsible for ensuring that all of its products comply with cGMPs and are not adulterated for failure to comply with cGMPs and are not misbranded.

595. The Supplier Requirements mandate that all suppliers must provide "transparency" about the facilities used to produce any materials sold in Walmart stores.[211]

596. Walmart claims that the transparency "allows Walmart to assess supply chain risk, monitor for compliance…and deploy resources in a risk-based manner."[212]

597. In order to ship any pharmaceutical product into any of Walmart's Pharmacy Distribution Centers, Walmart claims that the supplier must meet or exceed all applicable laws and requirements, as well as adhere to any additional requirements stated in the agreement.[213]

598. Walmart also claims that "Facility disclosure is essential to achieving true supply chain transparency." To this end, Walmart requires that each facility that engages in the

[209] https://cdn.corporate.walmart.com/cc/a8/5def88ed41bd82ece9d82124c4ce/final-02212017-prescription-product-supplier-requirements.pdf (last accessed Jan. 26, 2021)

[210] https://cdn.corporate.walmart.com/ad/a5/af4737574b789a79f0f970a95668/health-wellness-product-safety-requirements.pdf (last accessed Feb. 1, 2021).

[211] https://one.walmart.com/content/dam/responsiblesourcing/guidancedocuments/disclosure_policy_and_guidance-/Resource_DisclosurePolicyGuidance_ENG.pdf (last accessed Jan. 26, 2021)

[212] https://one.walmart.com/content/dam/responsiblesourcing/guidancedocuments/disclosure_policy_and_guidance-/Resource_DisclosurePolicyGuidance_ENG.pdf (last accessed Jan. 26, 2021)

[213] https://cdn.corporate.walmart.com/cc/a8/5def88ed41bd82ece9d82124c4ce/final-02212017-prescription-product-supplier-requirements.pdf (last accessed Jan. 26, 2021).

manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of sourced product must be disclosed to Walmart's "Health & Wellness Product Safety" department.[214]

599. Pursuant to FDA requirements that the PLD is responsible for the manufacture and distribution of its private-label products, Walmart requires its suppliers to provide:

> a third party certification and audit showing conformance with current FDA Good Manufacturing Practices (cGMP) specific for the type of products manufactured, prepared, propagated, compounded, processed, stored, packaged, or labeled in each respective facility or operation. This means that each facility disclosed as outlined under the Factory & Facility Disclosure section must provide cGMP certification and cGMP conformance audit documentation by a Walmart approved third party auditing body annually to Health & Wellness Product Safety. Third party cGMP audits and certifications are in addition to any audits required by Walmart's Responsible Sourcing team.[215]

600. Audit results containing "[i]tems showing non-conformance to standards will require submission of corrective measures acceptable to Health & Wellness Product Safety in order to receive approval" by Walmart.[216]

601. As part of its Equate OTC product line, Walmart sold ranitidine.

602. An example of an Equate label for Walmart's store-brand or private-label ranitidine follows:[217]

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[214] https://cdn.corporate.walmart.com/cc/a8/5def88ed41bd82ece9d82124c4ce/final-02212017-prescription-product-supplier-requirements.pdf (last accessed Jan. 26, 2021).

[215] *Id.* at 7.

[216] *Id.* at 8.

[217] https://www.walmart.com/grocery/ip/Equate-Maximum-Strength-Acid-Reducer-Ranitidine-Tablets-150-mg-220-Ct/24548560?athcpid=24548560&athpgid=similaritems&athcgid=null&athznid=null&athieid=null&athstid=CS014&athguid=19f5a29c-716c-4e72-98be-a41483b2e8eb&athena=true (last accessed Feb. 1, 2021).

603. Walmart's Equate ranitidine products can be identified by the unique labeler code assigned to Walmart by the FDA: 49035. Any NDC starting with 49035 is a Walmart private-label product.

604. A list of the Equate ranitidine products sold by Walmart as the PLD includes, *inter alia*:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Equate Ranitidine (Walmart)						
	150 mg	24 tablet pack	49035-608-02	ANDA091429	Perrigo	2/12/2012
	150 mg	90 tablet bottle	49035-608-75	ANDA091429	Perrigo	2/12/2012
	150 mg	65 tablet bottle	49035-800-09	ANDA091429	Perrigo	2/22/2013
	150 mg	90 tablet bottle	49035-800-75	ANDA091429	Perrigo	2/22/2013
	150 mg	65 tablet, 2 bottles in 1 carton	49035-800-81	ANDA091429	Perrigo	2/22/2013
	75 mg	150 tablet bottle	49035-876-47	ANDA076195	Perrigo	5/19/2017
	150 mg	65 tablet, 2 bottles in 1 carton	49035-404-13	ANDA078192	Dr. Reddys Labs Ltd	1/5/2010
	150 mg	24 tablet bottle	49035-404-34	ANDA078192	Dr. Reddys Labs Ltd	1/5/2010
	150 mg	65 tablet bottle	49035-404-61	ANDA078192	Dr. Reddys Labs Ltd	1/5/2010
	150 mg	220 tablet bottle	49035-404-65	ANDA078192	Dr. Reddys Labs Ltd	1/5/2010
	150 mg	65 tablet bottle	49035-117-06	ANDA200172	Apotex Inc	6/29/2017
	150 mg	65 tablet bottle	49035-852-09	ANDA091429	Perrigo	2/12/2012
	75 mg	30 tablet bottle	49035-353-30	ANDA201745	Strides Pharma	7/10/2012
	75 mg	150 tablet bottle	49035-353-55	ANDA201745	Strides Pharma	7/10/2012
	75 mg	10 tablet blister pack	49035-353-69	ANDA201745	Strides Pharma	7/10/2012

605. Walmart contracted with Perrigo, Dr. Reddy's Laboratories, Apotex, and Strides to manufacture its Equate ranitidine products.

606. Delegating manufacturing or testing operations for Equate ranitidine to other companies did not exonerate Walmart as the PLD from its regulatory requirements to establish a system of production and process controls to ensure its private-label products were not adulterated or misbranded prior to sale.

ii. Walmart's Failure to Warn and Misrepresentations with Regard to the Labels

607. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

608. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

609. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Walmart had a duty and was obligated to ensure that its ranitidine was properly stored,

handled, and warehoused by Walmart or its suppliers.

610. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[218] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

611. Nothing prevented Walmart from, on its own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Walmart from ensuring that ranitidine was not exposed to humidity or moisture.

612. At no time did Walmart attempt to change, or cause its suppliers to attempt to change, the Equate ranitidine label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Equate ranitidine products would not break down into NDMA prior to human consumption.

613. An example of an Equate label reflecting that expiration dates were included on the packaging follows:

[218] Woodcock Letter, *supra* note 95.

614. Based on the public scientific information, Walmart knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

615. At no time did Walmart change its Equate ranitidine label to shorten the expiration date. Walmart had the ability to cause its suppliers to unilaterally make such label changes for Equate ranitidine without prior FDA approval pursuant to the CBE regulation. Had Walmart attempted such label changes, the FDA would not have rejected them.

616. Because Walmart failed to include appropriate expiration dates on its products, Walmart failed to warn regarding and made false statements in the labeling of its products.

iii. Walmart's Failure to Warn and Misrepresentations with Respect to its Packaging

617. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**
>
> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

618. As alleged above, each PLD was required to conduct, or cause its contract manufacturer to conduct, stability testing, which was required to take the container into account.

619. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

620. Walmart knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

621. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

622. A substantial factor in NDMA formation was the container system Walmart chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

623. A different container would have reduced the amount of NDMA Plaintiffs

consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

624. Walmart could have changed, or caused its contract manufacturers to change, the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[219] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[220]

625. Walmart was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[221]

626. A reasonably prudent PLD would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

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[219] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[220] *See id.* at 20–21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

[221] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

627. As reflected in the chart above, and as an example only, Walmart sold its Equate ranitidine product in bottles with as many as 220 tablets.

628. A copy of the label for the Equate ranitidine product with 220 tablets follows:

629. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

630. Because Walmart failed to package its products in appropriate container sizes, Walmart failed to warn regarding and made false statements in the packaging of its products. Walmart's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Walmart made conscious decisions not to change the containers for its Ranitidine-Containing Products.

5. Store-Brand Manufacturer Defendants' Failure to Warn and Misrepresentations in the Labeling of Ranitidine-Containing Products

631. The Store-Brand Manufacturer Defendants (or CMOs) are Apotex, Dr. Reddy's,

Perrigo, and Strides.

632. A PLD[222] contracts with a CMO to manufacture and process a drug.

633. A CMO, or Store-Brand Manufacturer Defendant for purposes of this complaint, is typically required by contract or supplier agreement with the PLD to comply with cGMPs, ensure that the private-label drugs are not adulterated for failure to comply with cGMPs, and are not misbranded.

634. Consumers of the private-label drug are third-party beneficiaries of the contract between the PLD and CMO, i.e., between the Store-Brand Defendant and Store-Brand Manufacturer Defendant.

635. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[223] and conform to requirements governing the appearance of the label.[224]

636. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[225] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

637. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[226]

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[222] 21 C.F.R. §207.1.

[223] 21 C.F.R. §201.5.

[224] *Id.*, §201.15.

[225] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).

[226] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

638. All Store-Brand Manufacturer Defendants are also responsible for conducting stability testing, by agreement with the PLDs and pursuant to federal law, which testing must be "designed to assess the stability characteristics of drug products."[227] Store-Brand Manufacturer Defendants must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[228]

639. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[229] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[230] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166."[231]

640. Notably, while generic medications must have the same active ingredients as their branded counterparts, the inactive ingredients, or excipients, may not necessarily be identical. For this reason, the stability of each generic drug may differ.

641. Each manufacturer must therefore conduct its own tests to determine and set

[227] 21 C.F.R. §211.166(a).

[228] *Id.*

[229] *Id.*

[230] *Id.*, §211.137(a).

[231] *Id.*, §211.137(b).

accurate retest or expiration dates.

642. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[232]

643. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[233]

644. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.234

645. Some of the requirements in those regulations require FDA approval before implementing a label change.[235]

646. But the FDA has long recognized a CBE supplement that permits a manufacturer

[232] 43 Fed. Reg. 45059 (Sept. 29, 1978).

[233] 21 C.F.R. §211.166(b).

[234] *See id.*, §314.97(a) (requiring generics to comply with §§314.70, 314.71).

[235] *Id.*, §314.70(b).

to make immediate changes, subject to the FDA's post-change review.[236]

647. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[237] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[238]

648. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[239]—or to ensure that the drug is shipped and stored under appropriate conditions.

649. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."[240]

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[236] *Id.*, §314.70(c)(3), (c)(6).

[237] *Id.*, §314.70(c)(6)(i).

[238] 65 Fed. Reg. 83042 (Dec. 29, 2000).

[239] 21 C.F.R. §211.137(a).

[240] *Id.*, §314.70(c)(6)(iii)(A), (C), (D).

650. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[241]

651. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."[242]

652. At no time did any Store-Brand Manufacturer Defendant attempt to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

653. At no time did any Store-Brand Manufacturer Defendant attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

654. Based on the public scientific information, the Store-Brand Manufacturer Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

655. At no time did any Store-Brand Manufacturer Defendant change its label to shorten the expiration date. Store-Brand Manufacturer Defendants had the ability to unilaterally make

[241] *Id.*, §314.70 (d)(2)(ix).

[242] *Id.*, §314.70 (d)(2)(vi); *see also id.*, §314.70(d)(2)(vii), (x).

such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Store-Brand Manufacturer Defendant attempted such label changes, the FDA would not have rejected them.

656. Because they failed to include appropriate expiration dates on their products, Store-Brand Manufacturer Defendants made false statements in the labeling of their products.

a. Apotex's Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Apotex is a Contract Manufacturing Organization for the Private-Label Distributors Walmart, Walgreens, and Rite Aid.

657. Apotex is a CMO that contracted with multiple PLDs, including Walmart, Walgreens, and Rite Aid.

658. Apotex launched its "Private Label Division" in 2004, and launched its first OTC private label in the U.S. retail market in 2012. At that time Apotex's Private Label Division renamed the division "Apotex Consumer Products (ACP)."[243]

659. The Apotex Consumer Products division is focused on "supporting Private Label strategies to increase retail margins and drive [retail] client retention."[244]

660. Apotex maintains a Code of Conduct, which covers, *inter alia*, compliance with applicable laws and regulations. For example, the Code of Conduct provides: "As part of our quality standards, we are fully committed to ensuring our products are in full compliance with our rigorous internal standards, all application regulations, and GxP[1]. This commitment applies

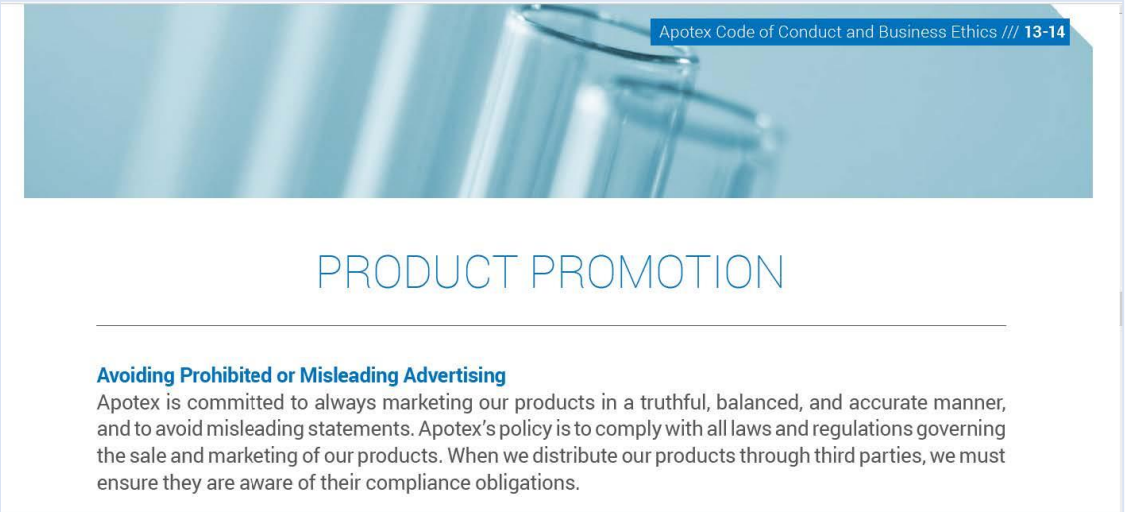
[243] http://www.apotexconsumerproducts.ca/ (last accessed Feb. 7, 2021).

[244] http://www.apotexconsumerproducts.ca/ (last accessed Feb. 7, 2021).

equally to products produced in our facilities and those supplied by third-party manufacturers."245

661. The footnote to "GxP" explains that "GxP collectively denotes Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Pharmacovigilance Practice (GVP) regulations."

662. Apotex's Code of Conduct further provides:



663. Apotex contracted with Walmart to manufacture Equate ranitidine products, including the following:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Equate Ranitidine (Walmart)						
	150 mg	65 tablet bottle	49035-117-06	ANDA200172	Apotex	6/29/2017

664. Apotex contracted with Walgreens to manufacture Wal-Zan ranitidine products, including:

[245] https://www1.apotex.com/docs/librariesprovider3/business-ethics/code-of-conduct-en.pdf?sfvrsn=3bc170ed_18, at p. 13 (last accessed Feb. 7, 2021).

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Wal-Zan Ranitidine						
	150 mg	65 tablet bottle	0363-1030-01	ANDA200172	Apotex	7/31/2015
	150 mg	24 tablet bottle	0363-1030-02	ANDA200172	Apotex	7/31/2015
	150 mg	50 tablet bottle	0363-1030-05	ANDA200172	Apotex	7/31/2015
	150 mg	65 tablet bottle	0363-1030-06	ANDA200172	Apotex	7/31/2015
	150 mg	200 tablet bottle	0363-1030-07	ANDA200172	Apotex	7/31/2015
	150 mg	95 tablet bottle	0363-1030-09	ANDA200172	Apotex	7/31/2015
	75 mg	80 tablet bottle	0363-1029-08	ANDA075167	Apotex	7/31/2015

665. Apotex contracted with Rite Aid to manufacture Rite Aid ranitidine products, including:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Rite Aid Ranitidine						
	150 mg	95 tablet bottle	11822-4727-3	ANDA200172	Apotex	6/26/2017
	150 mg	24 tablet bottle	11822-6051-8	ANDA200172	Apotex	6/26/2017
	150 mg	50 tablet bottle	11822-6052-1	ANDA200172	Apotex	6/26/2017
	150 mg	65 tablet bottle	11822-6052-2	ANDA200172	Apotex	6/26/2017
	150 mg	24 tablet bottle	11822-6107-4	ANDA200172	Apotex	6/30/2017

666. Each of the PLDs contracted with Apotex, and Apotex agreed, to ensure that each of the private-label ranitidine products it manufactured complied with cGMPs and were not adulterated for failure to comply with cGMPs and were not misbranded.

667. Each of the PLDs contracted with Apotex, and Apotex agreed, to provide a third-party certification and submit to audits showing conformance with FDA CGMP specific for the private label ranitidine products.

ii. Despite Apotex's Agreements to Comply with cGMPs, Apotex Aas Repeatedly Cited by the FDA.

668. The issues with the facility Apotex used to manufacture Ranitidine-Containing Products were documented in a pair of FDA warning letters in 2009 and 2010 regarding Apotex's compliance with cGMPs.[246]

669. The FDA stated that its inspection noted a "documented" practice of "repackaging and assigning new batch numbers to products that failed the Acceptable Quality Level ("AQL") test.

670. As an example of this practice, the FDA specifically identified ranitidine. The FDA wrote that:

671. For example, desiccant batch #HK8805 was used in approximately 76 different products, 11 of which failed the AQL desiccant leaking test. These 11 lots of contaminated Ranitidine Film Coated tablets 150 mg were initially rejected. However, 10 of these 11 lots were repackaged into 500 count bottles using a new lot of desiccant, and assigned a new batch number. These lots were then released for distribution without assessing the potential impact the leaking desiccant could have on product quality. You stated in your response that examination of retain samples for the 11 lots did not confirm the presence of leaky desiccant. However, it is possible that the absence of defective desiccant may be related to the limited number of retain samples examined. In your response to this letter please include a justification for the sample size and the corrective actions you have implemented to prevent reoccurrence of these types of events.[247]

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[246] http://fda-warning-letters.blogspot.com/2010/03/apotex-inc-32910.html.

[247] http://fda-warning-letters.blogspot.com/2010/03/apotex-inc-32910.html (last accessed Feb. 13, 2021). While Plaintiffs have included this warning letter here, the warning letter may be applicable to prescription generic ranitidine. Plaintiffs reserve the right to amend this allegation as further information is learned in discovery.

672. This was not the only issue the FDA noted at that time regarding ranitidine. Indeed, the FDA stated that during a March 2008 inspection, "a yellow contaminant was found during the production of Ranitidine HCL batch #HV9588 that led to the rejection of the batch." However, the FDA noted that the investigation into this yellow contaminant was not expanded to other lots manufactured by the same equipment prior to March 31, 2008.[248]

673. Apotex continued to have issues with the FDA and received an astounding four warning letters during the years it was manufacturing Ranitidine-Containing Products.

674. For example, in a 2012 Warning Letter, the FDA wrote that the "evidence suggests that Apotex has failed to implement adequate global and sustainable corrective and preventative actions" and that it "continues to manufacture and distribute pharmaceutical product without upholding its legal obligation to comply with cGMP."[249]

675. A warning letter issued in 2015 called into question Apotex's stability program, necessary to ensure that drug remained stable and safe throughout the expiration date. Indeed, the FDA documented multiple incidents of performing "trial" testing of samples, disregarding test results and reporting only those results that were favorable.[250]

676. The FDA also found that Apotex "failed to follow written procedures applicable to the quality control unit" and that the "quality control unit failed to review and approve all drug production and control records to determine compliance with all established, approved written

[248] http://fda-warning-letters.blogspot.com/2010/03/apotex-inc-32910.html.

[249] https://www.gmp-navigator.com/mygmp/mikrobiologie-sterilherstellung-hygiene/warning-letters-sterilfertigung?file=files/eca/userFiles/mygmp-guidelines/13-02-21-apotex.PDF.

[250] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apotex-research-private-limited-437669-01302015.

procedures before a batch is released or distributed."[251]

677. In 2018, Apotex received yet another warning letter, which simply repeated the same observations the FDA had made in its 2008 and 2009 warning letters, which had gone uncorrected for over a decade. The warning letter included observations that:

(a) Apotex failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch had already been distributed; and

(b) Apotex failed to establish valid in-process specifications.[252]

678. The FDA also found that the problems were more endemic to the overall corporate operation, finding that Apotex's quality unit did not "fully exercise authority such as ensuring that appropriate investigations are performed with sound conclusions, identifying root causes, and supporting scientific justification."[253]

679. The FDA also noted that the company's overall quality systems were "inadequate."[254]

680. In this letter, the FDA repeated the history of similar cGMP violations, and the fact that the FDA had previously communicated about the "need for appropriate and global quality oversight and control over the manufacture" of their products.[255]

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[251] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apotex-research-private-limited-437669-01302015

[252] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apotex-research-private-limited-547439-08092018

[253] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apotex-research-private-limited-547439-08092018

[254] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apotex-research-private-limited-547439-08092018

[255] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apotex-research-private-limited-547439-08092018

iii. Apotex's Failure to Warn and Misrepresentations in the Labeling of Ranitidine Products

681. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

682. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

683. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendant had a duty and was obligated to properly store, handle, and warehouse ranitidine.

684. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[256] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also

[256] Woodcock Letter, *supra* note 95.

showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

685. Nothing prevented Apotex from, on its own, taking actions to prevent accumulation of NDMA in the private-label Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Apotex from ensuring that ranitidine was not exposed to humidity or moisture.

686. At no time did Apotex attempt to include a warning on the labels for the private-label Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

687. At no time did Apotex attempt to change the private-label ranitidine labels to delete a false or misleading expiration date, or to add a proper expiration date to ensure that the private-label ranitidine products would not break down into NDMA prior to human consumption.

688. The labels on the PLD products manufactured by Apotex or lists referenced above also reflect that Apotex packaged the store-branded ranitidine in large quantities. Because of the unstable nature of ranitidine, Apotex knew or should have known that packages containing large quantities were less likely to be used completely and stored properly by the expiration date, particularly when the expiration date on the label was extended beyond a safe and appropriate date. Further, the demand for large quantity packages caused Apotex to know that the use of ranitidine

was routine for most customers and not a one-time purchase or use.

689. Based on the public scientific information, Apotex knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

690. At no time did Apotex change the private-label ranitidine products to shorten the expiration date.

691. Apotex had the ability to unilaterally, or in conjunction with the PLDs, to make such label changes for the private-label ranitidine products without prior FDA approval pursuant to the CBE regulation. Had Apotex attempted such label changes, the FDA would not have rejected them.

692. Because it failed to include appropriate expiration dates on PLD ranitidine products, failed to provide proper storage instructions and failed to package the product in a manner that would lead to less risk of degradation and failed to warn of the inherent risks, Apotex failed to warn regarding and made false statements in the labeling of its private-label ranitidine products.

693. Because Apotex failed to include appropriate expiration dates on the private-label products it manufactured, Apotex failed to warn regarding and made false statements in the labeling of its products.

iv. Apotex's Failure to Warn and Misrepresentations in the Packaging.

694. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**

> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

695. As alleged above, each contract manufacturer was required pursuant to federal law and contract to conduct stability testing, which was required to take the container into account.

696. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

697. Apotex knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

698. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

699. A substantial factor in NDMA formation was the container system Apotex chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

700. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

701. Apotex could have changed, or consulted with its PLD to change, the container

system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[257] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[258]

702. Apotex was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[259]

703. A reasonably prudent contract manufacturer would have changed, or consulted with its PLDs to change, the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

704. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

705. Because Apotex failed to package its products in appropriate container sizes, Apotex failed to warn regarding and made false statements in the packaging of its private-label products.

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[257] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[258] *See id.* at 20–21 (only requiring pre-approval for *sterile* drug products, when moving *from* unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

[259] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

706. Apotex's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Apotex made conscious decisions not to change the containers for its Ranitidine-Containing Products.

b. Dr. Reddy's Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Dr. Reddy's Is a Contract Manufacturing Organization for the Private-Label Distributors Walmart, Walgreens, and CVS

707. Dr. Reddy's is a CMO that contracted with multiple PLDs, including Walmart, Walgreens, and CVS.

708. According to Dr. Reddy's, it manufactures and sells "Over-the-counter products: More than 170+ SKUs for private labels packaging presentations."[260]

709. According to Dr. Reddy's, its manufacturing facilities comply with regulatory and cGMP requirements of the United States, including quality and safety requirements set by the FDA.[261]

710. Dr. Reddy's represents that its product responsibility includes "the assessment of health and safety impacts of products, extends from product development to manufacture, to product release, and to post-launch."[262] The website explains:[263]

[260] https://www.drreddys.com/media/107298/otc_catalog.pdf (last accessed Feb. 7, 2021).

[261] https://www.drreddys.com/OurCitizenship/SustainabilityReports/2009/pr-regulatory compliance.html (last accessed Feb. 7, 2021).

[262] https://www.drreddys.com/OurCitizenship/SustainabilityReports/2009/pr-productsafety.html.

[263] https://www.drreddys.com/OurCitizenship/SustainabilityReports/2009/pr-productsafety.html.

711. Dr. Reddy's maintains a Code of Business Conduct & Ethics. Dr. Reddy's Code provides in part: "To ensure the safe and proper use of our products, information provided to our customers and healthcare professionals on the packaging label, inserts, local prescribing information, or sales and advertising material must be in compliance with all applicable laws, standards and regulations that apply to our products, and supported by scientific evidence where relevant."[264]

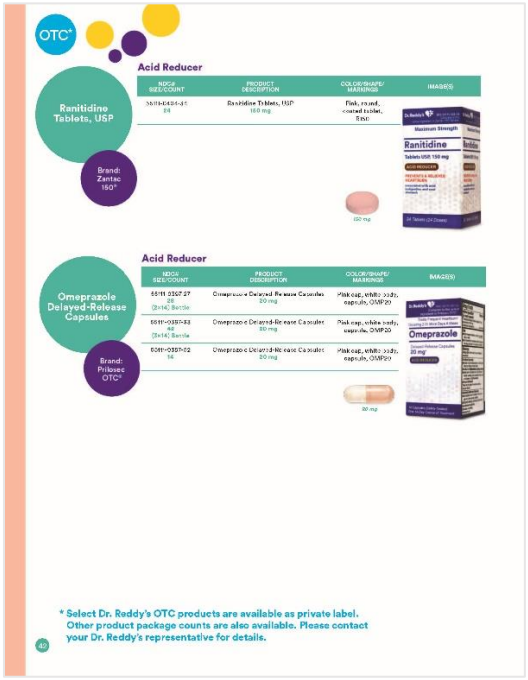
712. The Code further warrants: "We do not include false or misleading information or any misrepresentation, overstatement of the efficacy of our products, or statements that downplay or minimize the risks associated with our products."[265]

713. Dr. Reddy's manufactured Brand Zantac 150®, and as explained in its OTC

[264] https://www.drreddys.com/media/508807/cobe_booklet.pdf, at p.11 (last accessed Feb. 7, 2021).

[265] https://www.drreddys.com/media/508807/cobe_booklet.pdf, at p.11 (last accessed Feb. 7, 2021).

catalog: "Select Dr. Reddys OTC products are available as private label."[266]



714. Dr. Reddy's contracted with Walmart to manufacture several Equate ranitidine products, including the following:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Equate Ranitidine (Walmart)						
	150 mg	65 tablet, 2 bottles in 1 carton	49035-404-13	ANDA078192	Dr. Reddys	1/5/2010
	150 mg	24 tablet bottle	49035-404-34	ANDA078192	Dr. Reddys	1/5/2010
	150 mg	65 tablet bottle	49035-404-61	ANDA078192	Dr. Reddys	1/5/2010
	150 mg	220 tablet bottle	49035-404-65	ANDA078192	Dr. Reddys	1/5/2010

715. Dr. Reddy's contracted with Walgreens to manufacture several Wal-Zan ranitidine products, including:

[266] https://www.drreddys.com/media/107298/otc_catalog.pdf, at p. 42 (last accessed Feb. 7, 2021).

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Wal-Zan Ranitidine						
	150 mg	200 tablet bottle	0363-0010-01	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	36 tablet bottle	0363-0010-23	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	65 tablet bottle	0363-0010-26	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	32 tablet bottle	0363-0010-32	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	24 tablet bottle	0363-0010-34	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	50 tablet bottle	0363-0010-50	ANDA078192	Dr. Reddys	6/11/2011
	150 mg	65 tablet bottle	0363-0010-61	ANDA078192	Dr. Reddys	6/11/2011
	75 mg	30 tablet bottle	0363-0131-30	ANDA075294	Dr. Reddys	1/6/2014
	75 mg	45 tablet bottle	0363-0131-33	ANDA075294	Dr. Reddys	1/6/2014
	75 mg	80 tablet bottle	0363-0131-80	ANDA075294	Dr. Reddys	1/6/2014

716. Dr. Reddy's contracted with CVS to manufacture CVS Health ranitidine products, including:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
CVS Health Ranitidine (CVS)						
	150 mg	95 tablet bottle	69842-869-62	ANDA078192	Dr. Reddys	5/1/2010
	75 mg	30 tablet bottle	69842-871-30	ANDA075294	Dr. Reddys	7/1/2009
	75 mg	160 tablet bottle	69842-871-37	ANDA075294	Dr. Reddys	7/1/2009
	75 mg	80 tablet bottle	69842-871-80	ANDA075294	Dr. Reddys	7/1/2009

717. Each of the PLDs contracted with Dr. Reddy's, and Dr. Reddy's agreed, to ensure that each of the private-label ranitidine products it manufactured complied with cGMPs and were not adulterated for failure to comply with cGMPs and were not misbranded.

718. Each of the PLDs contracted with Dr. Reddy's, and Dr. Reddy's agreed, to provide a third-party certification and submit to audits showing conformance with FDA cGMP specific for the private label ranitidine products.

ii. Dr. Reddy's Failure to Warn and Misrepresentations in the Labeling of Ranitidine Products

719. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

720. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

721. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendant had a duty and was obligated to properly store, handle, and warehouse ranitidine.

722. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[267] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also

[267] Woodcock Letter, *supra* note 95.

showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

723. Nothing prevented Dr. Reddy's from, on its own, taking actions to prevent accumulation of NDMA in the private-label Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Dr. Reddy's from ensuring that ranitidine was not exposed to humidity or moisture.

724. At no time did Dr. Reddy's attempt to include a warning on the labels for the private-label Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

725. At no time did Dr. Reddy's attempt to change the private-label ranitidine labels to delete a false or misleading expiration date, or to add a proper expiration date to ensure that the private-label ranitidine products would not break down into NDMA prior to human consumption.

726. The labels on the PLD products manufactured by Dr. Reddy's or lists referenced above also reflect that Dr. Reddy's packaged the store-branded ranitidine in large quantities. Because of the unstable nature of ranitidine, Dr. Reddy's knew or should have known that packages containing large quantities were less likely to be used completely and stored properly by the expiration date, particularly when the expiration date on the label was extended beyond a safe and appropriate date. Further, the demand for large quantity packages caused Dr. Reddy's to know

that the use of ranitidine was routine for most customers and not a one-time purchase or use.

727. Based on the public scientific information, Dr. Reddy's knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

728. At no time did Dr. Reddy's change the private-label ranitidine products to shorten the expiration date.

729. Dr. Reddy's had the ability to unilaterally, or in conjunction with the PLDs, to make such label changes for the private-label ranitidine products without prior FDA approval pursuant to the CBE regulation. Had Dr. Reddy's attempted such label changes, the FDA would not have rejected them.

730. Because it failed to include appropriate expiration dates on PLD ranitidine products, failed to provide proper storage instructions and failed to package the product in a manner that would lead to less risk of degradation and failed to warn of the inherent risks, Dr. Reddy's failed to warn regarding and made false statements in the labeling of its private-label ranitidine products.

731. Because Dr. Reddy's failed to include appropriate expiration dates on the private-label products it manufactured, Dr. Reddy's failed to warn regarding and made false statements in the labeling of its products.

iii. Dr. Reddy's Failure to Warn and Misrepresentations in the Packaging

732. Title 21 U.S.C. § 352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**

> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

733. As alleged above, each contract manufacturer was required pursuant to federal law and contract to conduct stability testing, which was required to take the container into account.

734. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

735. Dr. Reddy's knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

736. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

737. A substantial factor in NDMA formation was the container system Dr. Reddy's chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

738. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

739. Dr. Reddy's could have changed, or consulted with its PLD to change, the container

system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[268] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[269]

740. Dr. Reddy's was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[270]

741. A reasonably prudent contract manufacturer would have changed, or consulted with its PLDs to change, the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

742. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

743. Because Dr. Reddy's failed to package its products in appropriate container sizes, Dr. Reddy's failed to warn regarding and made false statements in the packaging of its private-label products.

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[268] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (*e.g.*, grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[269] *See id.* at 20-21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

[270] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

744. Dr. Reddy's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Dr. Reddy's made conscious decisions not to change the containers for its Ranitidine-Containing Products.

c. Perrigo's Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Perrigo Is a Contract Manufacturing Organization for the Private-Label Distributors Walmart, Walgreens, CVS, and Rite Aid

745. Perrigo is a CMO that contracted with multiple PLDs, including Walmart, Walgreens, CVS, and Rite Aid.

746. According to Perrigo, its Consumer Self-Care Americas segment is the "Self-Care Private Label Leader," which "develops, manufactures, and markets over-the-counter (OTC) store brand products, primarily in the cough, cold, allergy, analgesics, gastrointestinal, smoking cessation, infant formula, and oral care."271

747. Perrigo admits that store-brand products, or private label products, "must meet the same quality standards for manufacturing and packaging as their costlier brand name counterparts."[272]

748. According to Perrigo, the purpose of private label products is to ensure "[c]onsumer confidence in buying OTC medications to prevent and treat acute and chronic conditions," while

[271] https://www.perrigo.com/consumer-self-care-americas-self-care-private-label-leader (last accessed Feb. 7, 2021).

[272] https://www.perrigo.com/consumer-self-care-americas-self-care-private-label-leader (last accessed Feb. 7, 2021).

satisfying retailers for which "[s]tore brand self-care is a major contributor to retailer profits."[273]

749. Perrigo explains that its expertise in mass customization for PLDs allows the company to take one SKU (or in this case ANDA) and translate it into hundreds of store-brand SKUs in multiple packaging and promotional configurations:[274]

750. Perrigo maintains a Code of Conduct, which covers, *inter alia*, compliance with applicable laws and regulations. For example, the Code of Conduct provides: "It is critical that we follow all quality, safety and Good Manufacturing policies and procedures," explaining "As a pharmaceutical company, we are governed by Current Good Manufacturing Practices and other country-specific quality requirements for developing, manufacturing and packaging our products."[275]

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[273] https://www.perrigo.com/consumer-self-care-americas-self-care-private-label-leader (last accessed Feb. 7, 2021).

[274] https://www.perrigo.com/consumer-self-care-americas-self-care-private-label-leader (last accessed Feb. 7, 2021).

[275] The Code of Conduct is available through a link on the page at https://www.perrigo.com/quality-product-safety (last accessed Feb. 7, 2021). Code of Conduct, at 7.

751. Perrigo's Code of Conduct further provides: "We follow rigorous laws, regulations and corporate policies to ensure that our packaging and promotional materials are accurate and adhere to appropriate marketing and advertising practices."[276]

752. An excerpt of the Perrigo Code of Conduct follows:

753. According to Perrigo, its customers "include major global, national, and regional retail drug, supermarket, and mass merchandise chains such as Walmart, CVS, Walgreens Boots Alliance, Rite Aid, Kroger, Target, Dollar General, Sam's Club, Costco, Petco, Petsmart, Aldi, Amazon, and major wholesalers, including McKesson, Cardinal Health, and Amerisource Bergen."[277]

[276] The Code of Conduct is available through a link on the page at https://www.perrigo.com/quality-product-safety (last accessed Feb. 7, 2021). Code of Conduct, at 7.

[277] Form 10-K (for the year ended Dec. 31, 2017), Perrigo Company LLC, available at https://content.edgar-online.com/ExternalLink/EDGAR/0001585364-18-000015.html?hash

754. Within Perrigo's Consumer Self-Care Americas segment, one of Perrigo's focuses is on digestive health, with a range of private label products to relieve upset stomach, diarrhea, heartburn, and indigestion.

755. Perrigo contracted with Walmart to manufacture several Equate ranitidine products, including the following:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Equate Ranitidine (Walmart)						
	150 mg	24 tablet pack	49035-608-02	ANDA091429	Perrigo	2/12/2012
	150 mg	90 tablet bottle	49035-608-75	ANDA091429	Perrigo	2/12/2012
	150 mg	65 tablet bottle	49035-800-09	ANDA091429	Perrigo	2/22/2013
	150 mg	90 tablet bottle	49035-800-75	ANDA091429	Perrigo	2/22/2013
	150 mg	65 tablet, 2 bottles in 1 carton	49035-800-81	ANDA091429	Perrigo	2/22/2013
	75 mg	150 tablet bottle	49035-876-47	ANDA076195	Perrigo	5/19/2017
	150 mg	65 tablet bottle	49035-852-09	ANDA091429	Perrigo	2/12/2012

756. Perrigo contracted with Walgreens to manufacture several Wal-Zan ranitidine products, including:

=97d278562bafad669bc43f3e9c76346345da67d63a6cf1330475b099ac1ff982&dest=CY17Q410KEX1068_HTM#CY17Q410KEX1068_HTM (last accessed Feb. 7, 2021).

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Wal-Zan Ranitidine						
	150 mg	95 tablet bottle	0363-0852-01	ANDA091429	Perrigo	1/11/2019
	150 mg	65 tablet bottle	0363-0852-09	ANDA091429	Perrigo	1/11/2019
	150 mg	1 tablet in 1 blister pack, 8 blister pack	0363-0852-51	ANDA091429	Perrigo	1/11/2019
	150 mg	1 tablet in 1 blister pack, 24 blister pack	0363-0852-62	ANDA091429	Perrigo	1/11/2019
	150 mg	200 tablet bottle	0363-0852-82	ANDA091429	Perrigo	1/11/2019
	75 mg	80 tablet bottle	0363-1876-27	ANDA076195	Perrigo	1/11/2019
	75 mg	30 tablet bottle	0363-1876-65	ANDA076195	Perrigo	1/11/2019
	150 mg	24 tablet bottle	0363-0950-02	ANDA091429	Perrigo	9/17/2011
	150 mg	85 tablet bottle	0363-0950-04	ANDA091429	Perrigo	9/17/2011
	150 mg	65 tablet bottle	0363-0950-09	ANDA091429	Perrigo	9/17/2011
	150 mg	32 tablet bottle	0363-0950-64	ANDA091429	Perrigo	9/17/2011

757. Perrigo contracted with CVS to manufacture CVS Health ranitidine products, including:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
CVS Health Ranitidine (CVS)						
	75 mg	160 tablet bottle	69842-293-06	ANDA076195	Perrigo	5/25/2018
	75 mg	80 tablet bottle	69842-293-27	ANDA076195	Perrigo	5/25/2018
	75 mg	30 tablet bottle	69842-293-65	ANDA076195	Perrigo	5/25/2018
	150 mg	95 tablet bottle	59779-540-01	ANDA091429	Perrigo	9/14/2015
	150 mg	24 tablet bottle	59779-540-02	ANDA091429	Perrigo	9/14/2015
	150 mg	65 tablet bottle	59779-540-09	ANDA091429	Perrigo	9/14/2015
	150 mg	200 tablet bottle	59779-540-82	ANDA091429	Perrigo	9/14/2015
	150 mg	95 tablet bottle	59779-950-01	ANDA091429	Perrigo	9/21/2011
	150 mg	65 tablet bottle	59779-950-09	ANDA091429	Perrigo	9/21/2011
	150 mg	1 tablet in blister pack, 8 blister pack	59779-950-51	ANDA091429	Perrigo	9/21/2011
	150 mg	1 tablet in blister pack, 24 blister pack	59779-950-62	ANDA091429	Perrigo	9/21/2011
	150 mg	32 tablet bottle	59779-950-64	ANDA091429	Perrigo	9/21/2011

758. Perrigo contracted with Rite Aid to manufacture Rite Aid ranitidine products, including:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Rite Aid Ranitidine						
	150 mg	1 tablet in 1 blister pack, 24 blister pack	11822-0852-1	ANDA091429	Perrigo	10/26/2011
	150 mg	50 tablet bottle	11822-0852-2	ANDA091429	Perrigo	10/26/2011
	150 mg	65 tablet botlte	11822-0852-3	ANDA091429	Perrigo	10/26/2011
	150 mg	95 tablet bottle	11822-0852-4	ANDA091429	Perrigo	10/26/2011
	150 mg	24 tablet bottle	11822-0852-5	ANDA091429	Perrigo	10/26/2011
	150 mg	24 tablet bottle	11822-0950-0	ANDA091429	Perrigo	12/7/2011
	150 mg	50 tablet bottle	11822-0950-1	ANDA091429	Perrigo	12/7/2011

759. Each of the PLDs contracted with Perrigo, and Perrigo agreed, to ensure that each of the private-label ranitidine products it manufactured complied with cGMPs and were not

adulterated for failure to comply with cGMPs and were not misbranded.

760. Each of the PLDs contracted with Perrigo, and Perrigo agreed, to provide a third-party certification and submit to audits showing conformance with FDA cGMP specific for the private label ranitidine products.

ii. Despite Perrigo's Agreements to Comply with cGMPs, Perrigo Was Repeatedly Cited by the FDA

761. Since 2000, Perrigo's manufacturing facilities have been inspected an astounding 31 times, and during each inspection, the FDA issued observations and findings of non-compliance with cGMPs.

762. The FDA's observations related to not only issues with the manufacture and testing of the product (including issues related to data integrity and inadequate quality assurance units) but also related to the storage of the product.

763. During a 2005 inspection, the FDA noted that Perrigo's Standard Operating Procedures related to the environmental circumstances of where materials were being held were inadequate because it did not "provide instructions for employees to follow in the event an out of specification result is obtained for temperature and/or humidity to ensure that an investigation" is initiated.[278]

764. Over ten years later, the FDA noted more temperature related issues at this particular facility, finding that drug products were not being stored "under appropriate conditions of temperature so that their identity, strength, quality and purity are not affected."[279]

[278] FDA Form 483, Perrigo New York (FEI: 2450054), Aug. 31, 2006, released pursuant to FOIA request.

[279] FDA Form 483, Perrigo New York (FEI: 2450054), Mar. 8, 2017, released pursuant to FOIA request.

765. The FDA found that Perrigo's temperature mapping studies in the raw material warehouse were not conducted in a manner that supported the identification of "worst case temperature locations."[280]

766. In 2019, the FDA observed that Perrigo's investigations of an "unexplained discrepancy and failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product."[281]

767. As it relates to the ongoing stability of its drug products, the FDA found that Perrigo had not investigated whether the methods used in ongoing stability studies which were validated prior to 2017 "are stability indicating" and whether the method is able to "detect all potential impurities."[282]

768. During a 2019 inspection of a facility in Holland, Michigan, the FDA noted that Perrigo lacked procedures and controls to keep and maintain documents containing data generated during GMP activities.[283]

769. As an example of this deficiency, the FDA noted that discarded batch packaging records had been seen in "shred bins."[284]

[280] FDA Form 483, Perrigo New York (FEI: 2450054), Mar. 8, 2017, released pursuant to FOIA request.

[281] FDA Form 483, Perrigo Company PLC (FEI: 1811666), Jan. 17, 2019, released pursuant to FOIA request.

[282] FDA Form 483, Perrigo Company PLC (FEI: 1811666), Jan. 17, 2019, released pursuant to FOIA request.

[283] FDA Form 483, L. Perrigo Company (FEI: 1000518646), Oct. 22, 2019, released pursuant to FOIA request.

[284] FDA Form 483, L. Perrigo Company (FEI: 1000518646), Oct. 22, 2019, released pursuant to FOIA request.

iii. Perrigo's Failure to Warn and Misrepresentations in the Labels for the Private-Label Ranitidine Products

770. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

771. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

772. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendant had a duty and was obligated to properly store, handle, and warehouse ranitidine.

773. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[285] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also

[285] Woodcock Letter, *supra* note 95.

showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

774. Nothing prevented Perrigo from, on its own, taking actions to prevent accumulation of NDMA in the private-label Ranitidine-Containing Products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Perrigo from ensuring that ranitidine was not exposed to humidity or moisture.

775. At no time did Perrigo attempt to include a warning on the labels for the private-label Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

776. At no time did Perrigo attempt to change the private-label ranitidine labels to delete a false or misleading expiration date, or to add a proper expiration date to ensure that the private-label ranitidine products would not break down into NDMA prior to human consumption.

777. The labels on the PLD products manufactured by Perrigo or lists referenced above also reflect that Perrigo packaged the store-branded ranitidine in large quantities. Because of the unstable nature of ranitidine, Perrigo knew or should have known that packages containing large quantities were less likely to be used completely and stored properly by the expiration date, particularly when the expiration date on the label was extended beyond a safe and appropriate date. Further, the demand for large quantity packages caused Perrigo to know that the use of ranitidine

was routine for most customers and not a one-time purchase or use.

778. Based on the public scientific information, Perrigo knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

779. At no time did Perrigo change the private-label ranitidine products to shorten the expiration date.

780. Perrigo had the ability to unilaterally, or in conjunction with the PLDs, to make such label changes for the private-label ranitidine products without prior FDA approval pursuant to the CBE regulation. Had Perrigo attempted such label changes, the FDA would not have rejected them.

781. Because it failed to include appropriate expiration dates on PLD ranitidine products, failed to provide proper storage instructions and failed to package the product in a manner that would lead to less risk of degradation and failed to warn of the inherent risks, Perrigo failed to warn regarding and made false statements in the labeling of its private-label ranitidine products.

782. Because Perrigo failed to include appropriate expiration dates on the private-label products it manufactured, Perrigo failed to warn regarding and made false statements in the labeling of its products.

iv. Perrigo's Failure to Warn and Misrepresentations in Packaging

783. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**

> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;….

(emphasis in original).

784. As alleged above, each contract manufacturer was required pursuant to federal law and contract to conduct stability testing, which was required to take the container into account.

785. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

786. Perrigo knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

787. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

788. A substantial factor in NDMA formation was the container system Perrigo chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

789. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

790. Perrigo could have changed, or consulted with its PLD to change, the container

system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[286] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes-Being Effected regulation.[287]

791. Perrigo was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[288]

792. A reasonably prudent contract manufacturer would have changed, or consulted with its PLDs to change, the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

793. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

794. Because Perrigo failed to package its products in appropriate container sizes, Perrigo failed to warn regarding and made false statements in the packaging of its private-label products.

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[286] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (*e.g.*, grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

[287] *See id.* at 20-21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

[288] *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

795. Perrigo's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Perrigo made conscious decisions not to change the containers for its Ranitidine-Containing Products.

d. Strides' Failure to Warn and Misrepresentations in the Labeling and Packaging of OTC Ranitidine-Containing Products

i. Strides Is a Contract Manufacturing Organization for the Private-Label Distributors Walmart, Walgreens, CVS, and Rite Aid

796. Strides is a CMO that contracted with multiple PLDs, including Walmart, Walgreens, CVS, and Rite Aid.

797. Strides contends that it has a "Clear vision of providing quality healthcare products to the market both in Prescription, Private label, OTC, and consumer health markets."[289]

798. Strides contracted with Walmart to manufacture several Equate ranitidine products, including the following:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Equate Ranitidine (Walmart)						
	75 mg	30 tablet bottle	49035-353-30	ANDA201745	Strides	7/10/2012
	75 mg	150 tablet bottle	49035-353-55	ANDA201745	Strides	7/10/2012
	75 mg	10 tablet blister pack	49035-353-69	ANDA201745	Strides	7/10/2012

799. Strides contracted with Walgreens to manufacture several Wal-Zan ranitidine products, including:

[289] https://www.strides.com/pharma-united-states.html (last accessed Feb. 7, 2021).

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Wal-Zan Ranitidine						
	75 mg	80 tablet bottle	0363-0352-08	ANDA201745	Strides	9/24/2013
	75 mg	30 tablet bottle	0363-0352-30	ANDA201745	Strides	9/24/2013
	150 mg	200 tablet bottle	0363-0362-02	ANDA200536	Strides	6/28/2011
	150 mg	24 tablet bottle	0363-0362-23	ANDA200536	Strides	6/28/2011
	150 mg	50 tablet bottle	0363-0362-50	ANDA200536	Strides	6/28/2011
	150 mg	65 tablet bottle	0363-0362-52	ANDA200536	Strides	6/28/2011
	150 mg	95 tablet bottle	0363-0362-95	ANDA200536	Strides	6/28/2011

800. Strides contracted with CVS to manufacture CVS Health ranitidine products, including:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
CVS Health Ranitidine (CVS)						
	75 mg	80 tablet bottle	59779-356-08	ANDA201745	Strides	9/9/2013
	75 mg	160 tablet bottle	59779-356-16	ANDA201745	Strides	9/9/2013
	75 mg	30 tablet blister pack	59779-356-31	ANDA201745	Strides	9/9/2013
	150 mg	200 tablet bottle	59779-354-20	ANDA200536	Strides	8/21/2012
	150 mg	24 tablet blister pack	59779-354-24	ANDA200536	Strides	8/21/2012
	150 mg	65 tablet bottle	59779-354-65	ANDA200536	Strides	8/21/2012
	150 mg	95 tablet bottle	59779-354-95	ANDA200536	Strides	8/21/2012

801. Strides contracted with Rite Aid to manufacture Rite Aid ranitidine products, including:

Product	Dosage	Package	NDC	ANDA	ANDA Manufacturer	Start Marketing Approval Date
Rite Aid Ranitidine						
	75 mg	30 tablet bottle	11822-6190-0	ANDA200536	Strides	6/15/2013
	75 mg	60 tablet bottle	11822-6190-1	ANDA200536	Strides	6/15/2013
	75 mg	80 tablet bottle	11822-6190-8	ANDA200536	Strides	6/15/2013

802. Each of the PLDs contracted with Strides, and Strides agreed, to ensure that each of the private-label ranitidine products it manufactured complied with cGMPs and were not adulterated for failure to comply with cGMPs and were not misbranded.

803. Each of the PLDs contracted with Strides, and Strides agreed, to provide a third-party certification and submit to audits showing conformance with FDA cGMP specific for the private label ranitidine products.

ii. Despite Strides' Agreements to Comply with cGMPs, Apotex Was Repeatedly Cited by the FDA

804. The FDA has repeatedly noted a slew of violations of cGMPs at Strides' manufacturing facilities over the years leading up to a recall of Ranitidine-Containing Products in 2019.

805. For example, during a 2014 inspection of one of the facilities used by Strides to manufacture Ranitidine-Containing Products in Bangalore, India, the FDA made four critical observations about issues with Strides' manufacturing practices and compliance with cGMPs.[290]

806. The FDA noted that Strides had not established control procedures to monitor the output and validate the performance of its manufacturing processes, resulting in "variability in the characteristics of in-process material and the drug product."[291]

807. The FDA also observed that written procedures were not being followed to conduct annual evaluations of "returned or salvaged drug products and investigations conducted for each

[290] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), Aug. 26, 2014, released pursuant to FOIA request.

[291] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), Aug. 26, 2014, released pursuant to FOIA request.

drug product."[292]

808. With respect to complaints made about the finished dose of its products, the FDA found that Strides' complaint records were "deficient" because they did not include the findings of the investigation and follow-up regarding those investigations.[293]

809. The FDA noted that deficient complaint investigations appeared to be a "pattern" of problematic behavior at this Strides facility.[294]

810. Upon a return inspection of this particular facility in 2016, the FDA noted that the equipment used in the "manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use."[295]

811. An inspection of this same facility in 2017 yielded even more observations related to Strides' investigations into "unexplained discrepancies" about a drug product which was "sticking" and "melting" together. The FDA noted that Strides' investigation "did not arrive at the actual root cause" of the problem which resulted in finished dose product "sticking" and "melting" together, and further that Strides had not taken "appropriate corrective actions."[296]

812. Moreover, the FDA found that Strides lacked the "written procedures for

[292] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), Aug. 26, 2014, released pursuant to FOIA request.

[293] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), Aug. 26, 2014, released pursuant to FOIA request.

[294] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), Aug. 26, 2014, released pursuant to FOIA request.

[295] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), Feb. 19, 2016, released pursuant to FOIA request.

[296] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), May 26, 2017, released pursuant to FOIA request.

production and process controls" designed to assure that the drug products Strides manufactured had the "identity, strength, quality and purity they purport or are represented to possess."[297]

813. In 2019, Strides' issues with the FDA came to a head when the FDA issued the company a warning letter, its strongest rebuke.[298]

814. In the warning letter, the FDA summarized the "significant" violations of cGMP regulations, which included:

(a) Failure to establish an adequate control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products;

(b) Failure to thoroughly investigate any unexplained discrepancies or failures of a batch or any of its components to meet any of its specifications, regardless of whether the batch has already been distributed; and

(c) Data integrity issues related to its quality system, which did not adequately ensure the "accuracy and integrity of data to support the safety, effectiveness and quality of the drugs" manufactured by Strides.

iii. Strides' Failure to Warn and Misrepresentations in the Labeling of Ranitidine Products

815. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

816. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good

[297] FDA Form 483, Strides Arcolab Ltd (FEI: 3004554612), May 26, 2017, released pursuant to FOIA request.

[298] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/strides-pharma-science-limited-576722-07012019

manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

817. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendant had a duty and was obligated to properly store, handle, and warehouse ranitidine.

818. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[299] The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

819. Nothing prevented Strides from, on its own, taking actions to prevent accumulation of NDMA in the private-label Ranitidine-Containing Products by ensuring storage and transport

[299] Woodcock Letter, *supra* note 95.

at the lower end of the temperature range contained on the labels. Nothing prevented Strides from ensuring that ranitidine was not exposed to humidity or moisture.

820. At no time did Strides attempt to include a warning on the labels for the private-label Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

821. At no time did Strides attempt to change the private-label ranitidine labels to delete a false or misleading expiration date, or to add a proper expiration date to ensure that the private-label ranitidine products would not break down into NDMA prior to human consumption.

822. The labels on the PLD products manufactured by Strides or lists referenced above also reflect that Strides packaged the store-branded ranitidine in large quantities. Because of the unstable nature of ranitidine, Strides knew or should have known that packages containing large quantities were less likely to be used completely and stored properly by the expiration date, particularly when the expiration date on the label was extended beyond a safe and appropriate date. Further, the demand for large quantity packages caused Strides to know that the use of ranitidine was routine for most customers and not a one-time purchase or use.

823. Based on the public scientific information, Strides knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

824. At no time did Strides change the private-label ranitidine products to shorten the expiration date.

825. Strides had the ability to unilaterally, or in conjunction with the PLDs, to make such

label changes for the private-label ranitidine products without prior FDA approval pursuant to the CBE regulation. Had Strides attempted such label changes, the FDA would not have rejected them.

826. Because it failed to include appropriate expiration dates on PLD ranitidine products, failed to provide proper storage instructions and failed to package the product in a manner that would lead to less risk of degradation and failed to warn of the inherent risks, Strides failed to warn regarding and made false statements in the labeling of its private-label ranitidine products.

827. Because Strides failed to include appropriate expiration dates on the private-label products it manufactured, Strides failed to warn regarding and made false statements in the labeling of its products.

iv. Strides' Failure to Warn and Misrepresentations in the Packaging.

828. Title 21 U.S.C. §352(i)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (i) **DRUG; MISLEADING CONTAINER; IMITATION; OFFER FOR SALE UNDER ANOTHER NAME**
>
> (1) If it is a drug and its container is so made, formed, or filled as to be misleading;

(emphasis in original).

829. As alleged above, each contract manufacturer was required pursuant to federal law and contract to conduct stability testing, which was required to take the container into account.

830. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

831. Strides knew or should have known that ranitidine had an inherent risk of degrading

into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

832. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

833. A substantial factor in NDMA formation was the container system Strides chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

834. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

835. Strides could have changed, or consulted with its PLD to change, the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes-Being Effected regulation.[300] FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented

[300] *See* FDA, *Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1*, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

through the Changes-Being Effected regulation.[301]

836. Strides was not required to put its ranitidine in the same containers as the other store-brand OTC products, because the duty of sameness does not apply to containers. It applies only to the drug label.[302]

837. A reasonably prudent contract manufacturer would have changed, or consulted with its PLDs to change, the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

838. Further the demand for large quantity package sizes put Defendant on notice that purchases were made for regular and extended use, and not for a one-time occasion.

839. Because Strides failed to package its products in appropriate container sizes, Strides failed to warn regarding and made false statements in the packaging of its private-label products.

840. Strides' conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of its products. Strides made conscious decisions not to change the containers for its Ranitidine-Containing Products.

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301 *See id.* at 20–21 (only requiring pre-approval for ***sterile*** drug products, when moving ***from*** unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

302 *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug ….").

V. ADDITIONAL COUNT-SPECIFIC ALLEGATIONS

A. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR FAILURE TO WARN THROUGH WARNINGS AND PRECAUTIONS

841. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; and (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

842. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

843. To mitigate degradation of ranitidine into NDMA in the stomach, consumers should have been warned not to take ranitidine with or after meals or in combination with a high-nitrite diet. No Ranitidine-Containing Product contained this warning.

844. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could have been and should have been warned to consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g., not in a bathroom). No Ranitidine-Containing Product contained this warning.

845. To mitigate the risk of NDMA causing cancer, consumers should have been warned to consume ranitidine for only short periods of time. No Ranitidine-Containing Product warned that cancer could result from long-term ingestion of ranitidine.

846. Brand Manufacturer Defendants knew or should have known about each of these risks in time to warn consumers.

847. As was alleged in more detail above, in 1981 Dr. de Flora published the results of

experiments in The Lancet showing that ranitidine produced NDMA in combination with gastric fluid and nitrites. This study put all future manufacturers of ranitidine on notice of the risks of consuming ranitidine in combination with high-nitrite foods.

848. GSK responded in The Lancet in November 1981. This response shows that GSK was in fact aware of Dr. de Flora's research.

849. GSK told the FDA that Dr. de Flora's research has no "practical clinical significance."

850. GSK conducted another study around 1981 that found that ranitidine could cause nitrates to convert into nitrites in the human stomach, which, in combination with Dr. de Flora's research, would mean a heightened risk of NDMA formation. This should have sparked reconsideration of the claim that nitrites would not be high enough in the stomach for Dr. de Flora's research to have practical significance.

851. In April 1982, GSK performed a study [redacted]

852. After Zantac had been approved for marketing by the FDA, GSK conducted a study on how ranitidine breaks down in the human stomach and concluded that the amount of nitrosamines formed was low. That study was published in 1987. However, GSK used a less reliable test (a nitrogen oxide assay) designed for use in food and discarded two-thirds of the samples because they contained ranitidine (which the study claimed might produce a false positive).

853. In 1983, after GSK's flawed study, but before it was published, a University of Genoa study determined that ranitidine could react with nitrite and produce NDMA, which could induce DNA damage.

854. Also in 1983, Dr. de Flora published his complete findings, confirming his initial results about the risks of NDMA breakdown in the human stomach in combination with nitrites. GSK did not modify its position.

855. In 2002, a study indicated that NDMA was found in the urine and gastric fluid of children after taking ranitidine for four weeks.

856. In 2012, a study indicated that ranitidine may be a source of NDMA in drinking water.

857. In 2016, a Stanford University study suggested that NDMA amounts in humans increased after consuming ranitidine.

858. In 2019, Valisure tested ranitidine tablets to determine if they contained NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol developed for Valsartan, this method was validated to a lower limit of detection of 25 ng.[303] Valisure found when using the GC/MS headspace analysis method that ranitidine would transform into high levels of NDMA.

859. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under high temperatures.

860. Any Manufacturer Defendant could have studied ranitidine using the tests Valisure

[303] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

performed, and would have discovered that ranitidine transforms into NDMA when subjected to heat.

861. At all relevant times, Brand Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Brand Manufacturer Defendants.

862. Brand Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of the same, directly marketed the products to consumers and end users, including Plaintiffs, and, therefore, had a duty to warn of the risks associated with the use of ranitidine.

863. At all relevant times, Brand Manufacturer Defendants had a duty to properly manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Brand Manufacturer Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. Brand Manufacturer Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

864. Brand Manufacturer Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

865. At the time of manufacture, Brand Manufacturer Defendants could have provided

warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

866. At all relevant times, Brand Manufacturer Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Brand Manufacturer Defendants' Ranitidine-Containing Products.

867. Even though Brand Manufacturer Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to Ranitidine-Containing Products. The dangerous propensities of Ranitidine-Containing Products and the carcinogenic characteristics of NDMA, as described above, were known to Brand Manufacturer Defendants, or scientifically knowable to Brand Manufacturer Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

868. Brand Manufacturer Defendants knew or should have known that Ranitidine-Containing Products created significant risks of serious bodily harm to consumers, as alleged herein, and Brand Manufacturer Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and physicians of the risks of exposure to Ranitidine-Containing Products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in Ranitidine-Containing Products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

869. Brand Manufacturer Defendants possessed new information or new analyses of

existing information that empowered them unilaterally to change the warnings and precautions section of their Ranitidine-Containing Products' label.

870. Despite this ability, Brand Manufacturer Defendants failed to warn of the risks of NDMA and their Ranitidine-Containing Products in the warnings and precautions section of their Ranitidine-Containing Products' label.

871. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured. The warnings Plaintiffs and their doctors observed were not changed from when they left Defendants' control.

872. Plaintiffs were exposed to Defendants' Ranitidine-Containing Products without knowledge of their dangerous characteristics.

873. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

874. Plaintiffs could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Brand Manufacturer Defendants to know about and disclose serious health risks associated with using Defendants' products.

875. Brand Manufacturer Defendants knew or should have known that the minimal warnings disseminated with their Ranitidine-Containing Products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products

safe for their ordinary, intended and reasonably foreseeable uses.

876. The information that Brand Manufacturer Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

877. Had Brand Manufacturer Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products on the warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Brand Manufacturer Defendants' concealment of the dangers posed by their Ranitidine-Containing Products, Plaintiffs were not alerted, and so could not avert their injuries.

878. Brand Manufacturer Defendants' conduct, as described above, was reckless. Brand Manufacturer Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Products, and suppressed this knowledge from the general public. Brand Manufacturer Defendants made conscious decisions not to warn or inform the unsuspecting public. Brand Manufacturer Defendants' reckless conduct warrants an award of punitive damages.

879. Brand Manufacturer Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their Ranitidine-Containing Products' labels were a substantial factor in causing Plaintiffs' injuries.

B. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR FAILURE TO WARN THROUGH PROPER EXPIRATION DATES

880. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; and (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

881. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

882. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should be warned to consume ranitidine shortly after manufacturing. No Ranitidine-Containing Product contained this warning.

883. In fact, Ranitidine-Containing Products had expiration dating periods of one or two years, allowing gradual accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

884. Manufacturer Defendants (both brand and generic) and Store-Brand Defendants knew or should have known about each of these risks in time to warn consumers. Simple, widely available and cost-effective tests reveal these risks.

885. In setting expiration and/or retest dates for their ranitidine-containing drugs,

Manufacturer Defendants and Store-Brand Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. §211.137.

886. In setting the expiration and/or retest dates for their ranitidine-containing drugs, Manufacturer Defendants and Store-Brand Defendants were also required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. §211.166.

887. Storage conditions must account for conditions, including the storage container, heat, light, and humidity, among other things.

888. At all relevant times, each Defendant failed to adhere to their duties to set accurate expiration dates based upon stability testing that complied with the manufacturers' duties to account for these real-world conditions. These actions were under the ultimate control and supervision of the Manufacturer Defendants.

889. Brand Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA.

890. Generic Manufacturer Defendants and Store-Brand Defendants manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly marketed the products to consumers and end users, including Plaintiffs, and, therefore, had a duty to warn of the risks associated with the use of ranitidine.

891. At all relevant times, Generic Manufacturer Defendants and Store-Brand

Defendants manufactured, tested, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs. These actions were under the ultimate control and supervision of Generic Manufacturer Defendants, except as to the warning section of the label.

892. Generic Manufacturer Defendants and Store-Brand Defendants manufactured, tested, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of the same, knew and reasonably foresaw that their product would be substituted by custom or by law for a well-known product that was directly marketed to consumers and end users, including Plaintiffs. Generic Manufacturer Defendants and Store-Brand Defendants therefore had a duty to warn of the risks associated with the use of ranitidine.

893. Generic Manufacturer Defendants and Store-Brand Defendants had a duty to provide proper warnings to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Manufacturer Defendants, as a manufacturer of pharmaceutical medication, are held to the knowledge of an expert in the field.

894. Generic Manufacturer Defendants and Store-Brand Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates that were rooted in sufficient testing and based on real-world storage conditions.

895. At the time of manufacture and at other times before the ingestion of ranitidine, Generic Manufacturer Defendants and Store-Brand Defendants could have provided an expiration dating period for ranitidine that greatly reduced the shelf-life of the Ranitidine-Containing Product with time available to consume the product before higher NDMA levels were present. Manufacturer Defendants and Store-Brand Defendants knew or should have known of the

unreasonable risks of harm associated with the use of and/or exposure to ranitidine after months or years of degradation into NDMA.

896. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

897. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to Ranitidine-Containing Products. The dangerous propensities of Ranitidine-Containing Products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

898. Defendants knew or should have known that Ranitidine-Containing Products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and/or physicians of the risks of exposure to Ranitidine-Containing Products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in Ranitidine-Containing Products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

899. At all relevant times, the Ranitidine-Containing Products were defective at the time they left the Defendants' control. No extrinsic changes were made to alter the products Defendants manufactured and sold. The expiration dates Plaintiffs and their doctors observed were not

changed from when they left Defendants' control.

900. Plaintiffs were exposed to Defendants' Ranitidine-Containing Products without knowledge of their dangerous characteristics.

901. At all relevant times, Plaintiffs used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

902. Plaintiffs could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

903. Defendants knew or should have known that the expiration dating periods disseminated with their Ranitidine-Containing Products were inadequate because they were long enough for dangerous levels of NDMA to build up in ranitidine.

904. This alleged failure to warn is not limited to the information contained on the section of the Ranitidine-Containing Products' label devoted to health warnings. Defendants were able, in accord with federal law, to comply with relevant state law by providing a short expiration dating period that would accurately warn consumers not to consume ranitidine after significant portions of it had progressively deteriorated into NDMA. But Defendants did not disclose these known risks through any medium.

905. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used

alternative medication. However, as a result of Defendants' concealment of the dangers posed by their Ranitidine-Containing Products, Plaintiffs were not alerted, and so could not avert their injuries.

906. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products were a substantial factor in causing Plaintiffs' injuries.

C. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR FAILURE TO WARN THROUGH FDA

907. At all relevant times, Brand Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs. These actions were under the ultimate control and supervision of Brand Manufacturer Defendants.

908. Brand Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of the same, directly marketed the products to consumers and end users, including Plaintiffs, and, therefore, had a duty to warn of the risks associated with the use of ranitidine.

909. At all relevant times, Generic Manufacturer Defendants manufactured, tested,

labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs. These actions were under the ultimate control and supervision of Generic Manufacturer Defendants.

910. Generic Manufacturer Defendants manufactured, tested, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of the same, knew and reasonably foresaw that their product would be substituted by custom or by law for a well-known product that was directly marketed to consumers and end users, including Plaintiffs. Generic Manufacturer Defendants therefore had a duty to warn of the risks associated with the use of ranitidine.

911. Manufacturer Defendants (both brand and generic) had a duty to warn Plaintiffs of dangers associated with ranitidine.

912. At the time of manufacture and at other times before the ingestion of ranitidine, Manufacturer Defendants could have provided the warnings or instructions regarding ranitidine's risk of cancer because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

913. Manufacturer Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

914. At all relevant times, Manufacturer Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Manufacturer Defendants' Ranitidine-Containing Products.

915. Even though Manufacturer Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks

associated with use and exposure to Ranitidine-Containing Products. The dangerous propensities of Ranitidine-Containing Products and the carcinogenic characteristics of NDMA, as described above, were known to Manufacturer Defendants, or scientifically knowable to Manufacturer Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

916. At all relevant times, Manufacturer Defendants' Ranitidine-Containing Products were expected to and did reach Plaintiffs without a substantial change in their anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by the Brand Manufacturer or Generic Manufacturer Defendants.

917. Plaintiffs were exposed to Manufacturer Defendants' Ranitidine-Containing Products without knowledge of their dangerous characteristics. Plaintiffs could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of Manufacturer Defendants to know about and disclose serious health risks associated with using Manufacturer Defendants' products.

918. At all relevant times, Plaintiffs used and/or were exposed to the use of Manufacturer Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

919. Manufacturer Defendants knew or should have known that the minimal warnings disseminated with their Ranitidine-Containing Products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary,

intended and reasonably foreseeable uses.

920. The information that Manufacturer Defendants did provide or communicate failed to contain relevant warnings, expiration dates, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Manufacturer Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

921. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Manufacturer Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with ranitidine to the FDA.

922. Both Brand Manufacturer Defendants and Generic Manufacturer Defendants are required under federal law to submit adverse event reports. See 21 C.F.R. §314.80. These requirements place an affirmative obligation on manufacturers to seek out information about their products. Every manufacturer "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. … Any person subject to the reporting requirements under

paragraph (c) of this section must also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." 21 C.F.R. §314.80(b). Each Manufacturer Defendant systematically failed to submit adverse event reports about the cancer risks of ranitidine. Each Manufacturer Defendant failed to put in place procedures ensuring full compliance with their reporting obligations.

923. According to the FDA's Adverse Events Reporting System (FAERS) with data up to September 2020, 59% of all-time adverse events for branded and generic ranitidine were filed in 2020. Before 2019, the volume of adverse events reported for Ranitidine-Containing Products that mentioned cancer as a reaction was insignificant.

924. Both Brand Manufacturer Defendants and Generic Manufacturer Defendants also may, consistent with federal law, inform the FDA of new analyses of data, newly revealed risks, new testing, or other information about their drugs.

925. Upon information and belief, at all relevant times, Manufacturer Defendants failed to adhere to their pharmacovigilance obligations to collect, analyze, and report adverse events to consumers and physicians through the FDA.

926. Manufacturer Defendants, by failing to adequately warn of the risk of NDMA, failed to provide physicians and consumers (like Plaintiffs) with sufficient information for them to know enough to report adverse events when they occurred.

927. The failure by the Manufacturer Defendants to sufficiently report adverse events to the FDA prevented physicians and researchers from having access to accurate information about the true risks of Zantac and ranitidine.

928. Physicians can and did conduct studies about the risks of Zantac and ranitidine based upon the data available through the FAERS. Had the Manufacturer Defendants adequately

warned the FDA by putting in place sufficient pharmacovigilance programs and adequate warnings, physicians conducting studies would have been able to better ascertain, report, and publish literature on the true risks associated with ingesting Zantac and ranitidine.

929. Nonetheless, Defendants failed to inform the FDA of the risks of ranitidine breaking down into carcinogenic NDMA.

930. When the FDA was told of the risks of ranitidine in 2019, it promptly posted notices on its website, investigated the issue, and ordered a recall. The broader medical community became aware of, and reacted to, the cancer risks of ranitidine.

931. Had Manufacturer Defendants submitted adverse event reports concerning ranitidine's cancer risks or otherwise informed the FDA of those risks years earlier, the FDA would have acted similarly by publicizing and investigating the concerns, and, ultimately, ordering a recall. The medical community would also have been promptly aware of the risks. Plaintiffs' doctors would not have prescribed ranitidine in light of those risks and the availability of safe substitutes. Similarly, Plaintiffs would not have purchased and ingested ranitidine.

932. Had Manufacturer Defendants submitted adverse event reports concerning ranitidine's cancer risks or otherwise informed the FDA of those risks years earlier, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication.

933. However, as a result of Manufacturer Defendants' concealment of the dangers posed by their Ranitidine-Containing Products, Plaintiffs could not have averted their injuries.

934. Manufacturer Defendants' conduct, as described above, was reckless. Manufacturer Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Products,

and suppressed this knowledge from the general public and the FDA.

935. Manufacturer Defendants made conscious decisions not to warn or inform the unsuspecting public or FDA, though they could have done so. Manufacturer Defendants' reckless conduct warrants an award of punitive damages.

936. Manufacturer Defendants' failure to provide adequate warnings and instructions accompanying their Ranitidine-Containing Products were a substantial factor in causing Plaintiffs' injuries.

D. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS REGARDING NEGLIGENT PRODUCT CONTAINERS

937. As alleged above, each Manufacturer Defendant and Store-Brand Defendant was required to conduct stability testing, which was required to take the container into account.

938. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

939. Defendants knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

940. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

941. A substantial factor in NDMA formation was the container system manufacturers chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

942. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

943. Each Manufacturer Defendant and Store-Brand Defendant could have unilaterally changed the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes Being Effected regulation. *See* FDA, Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

944. FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes Being Effected regulation. *See id*. at 20–21 (only requiring pre-approval for sterile drug products, when moving from unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

945. Generic Manufacturer Defendants and Store-Brand Defendants were not required to put their generic ranitidine in the same containers as the branded product, because the duty of sameness does not apply to containers.

946. It applies only to the drug label. *See* 21 C.F.R. §314.94(a)(8)(iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for

the drug product must be the same as the labeling approved for the reference listed drug ….").

947. A reasonably prudent manufacturer would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

948. Instead, the Store-Brand Defendants sold their Store-BRandedr ranitidine products in large containers. By way of example, Walmart sold its Equate ranitidine product in bottles with as many as 220 tablets. Similarly, Walgreens sold its Wal-Zan ranitidine products in bottles with as many as 200 tablets. CVS also sold its ranitidine products, called CVS Health, in bottles with as many as 200 tablets.

949. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

950. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to change the containers for their Ranitidine-Containing Products.

E. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR NEGLIGENT STORAGE AND TRANSPORTATION

951. As alleged above, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

952. Brand Manufacturer Defendants, Generic Manufacturer Defendants and Store-Brand Defendants are well aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Brand Manufacturer Defendants and Generic Manufacturer Defendants are and were well aware of the importance of precise temperature control down to the degree as well as

the importance of precise humidity control. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

953. The temperature and humidity specifications placed on Ranitidine-Containing Products also affect the stability of Ranitidine-Containing Products.

954. NDMA forms due to chemical reactions in the human body, and degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and humidity is causing differing amounts of NDMA to form.

955. Defendants are aware that Ranitidine is highly sensitive to humidity and moisture. Ranitidine that is subjected to humidity and/or moisture, degrades quickly and forms excessive amount of NDMA.

956. Defendants must account for these heat and humidity conditions and specifications in order to set proper shipping, storage and handling policies as well as accurate retest and expiration dates.

957. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has much more NDMA when tested, and some has less.

958. Defendants admit that substantial variation exists in NDMA levels in their Ranitidine-Containing Products, and that levels increase over time but more so when subjected to heat and humidity.

959. Different Ranitidine-Containing Products listed slightly different storage and transportation requirements, but a common label requirement was “store at 20°C to 25°C (68°F to

77°F)" and "avoid excessive heat or humidity."

960. Manufacturer Defendants and Store-Brand Defendants transport finished drug product from their facilities to distributor warehouses, as well as storing finished drug products in their facilities.

961. Some Brand Manufacturer Defendants and Generic Manufacturer Defendants also purchase API, which they store at their facilities. Their agreements with API manufacturers govern how API is transported to them. The storage and transportation conditions of API is not dictated by the label for finished Ranitidine-Containing Products and may differ.

962. Upon information and belief, Manufacturer Defendants and Store-Brand Defendants systematically caused Ranitidine-Containing Products to be exposed to excessive levels of heat and/or humidity during manufacture, storage, shipping and handling that violated the instructions on the finished products' labels and caused ranitidine to degrade more quickly thereby increasing the levels of NDMA in the product.

963. Based upon the documents produced by Defendants and based upon further information and belief, the Manufacturer Defendants and Store-Brand Defendants failed to ensure that their finished Ranitidine-Containing Products were stored and transported safely and were not exposed to excessive heat and humidity.

964. Based upon the documents produced by Defendants and based upon further information and belief, the Manufacturer Defendants and Store-Brand Defendants failed to ensure that API they stored, transported, or over which they could control storage or transportation, were not exposed to excessive heat and humidity.

965. Upon information and belief, Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and/or humidity requirements on product labels. This

failure led to widespread noncompliance.

966. For example, Manufacturer Defendants shipped Ranitidine-Containing Products through the mail. This method of transportation – whether through the United States Postal Service or large common carriers such as FedEx and UPS – does not guarantee controlled temperature or humidity. Because of Manufacturer Defendants' and Store-Brand Defendants' choice to allow this method of transportation, Ranitidine-Containing Products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid. In addition, Manufacturer Defendants and Store-Brand Defendants failed to properly monitor temperature and/or humidity levels during storage and transport.

967. Based upon the documents produced by Defendants and based upon further information and belief, the Manufacturer Defendants and Store-Brand Defendants failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were stored and transported safely and were not exposed to excessive heat and humidity and systematically exposed ranitidine to excessive levels of heat and humidity that violated the instructions on the products' labels.

968. Defendants, directly or indirectly, transported, stored, handled, and/or sold Ranitidine-Containing Products that were used by Plaintiffs.

969. At all relevant times, Manufacturer Defendants and Store-Brand Defendants had a duty to exercise reasonable care in the storage and transportation of ranitidine API and Ranitidine-Containing Products to ensure the products were not unreasonably dangerous to consumers and users.

970. At all relevant times, Manufacturer Defendants and Store-Brand Defendants knew or should have known of the need for storing and transporting finished Ranitidine-Containing

Products within the labeled temperature range and at low humidity, and for storing and transporting Ranitidine-Containing Products and ranitidine API at a reasonable, low temperature that would prevent degradation, and at low humidity.

971. Manufacturer Defendants and Store-Brand Defendants ignored this risk. They did not ensure ranitidine API and Ranitidine-Containing Products were stored at low humidity or within the temperature range on the label. Instead, ranitidine API and Ranitidine-Containing Products were subjected to excessive humidity and/or heat during transportation and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

972. Ignoring the risks of degradation and NDMA forming was unreasonable and reckless.

973. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Ranitidine-Containing Products.

974. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

VI. PLAINTIFFS' USE OF RANITIDINE-CONTAINING PRODUCTS

975. Plaintiffs ingested Ranitidine-Containing Products at various times as part of their treatment for gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

976. Plaintiffs used Ranitidine-Containing Products designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants. Those products, unbeknownst to Plaintiffs, transformed into dangerous levels of NDMA.

977. Based on prevailing scientific evidence, exposure to NDMA caused by consuming Defendants' Ranitidine-Containing Products causes cancer in humans, including serious and potentially fatal Subject Cancers.

978. As a direct and proximate result of Defendants' unlawful conduct alleged herein, Plaintiffs and the Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

979. The latent injuries from which Plaintiffs the Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

980. The medical monitoring regime should include, but is not limited to, baseline tests and periodic diagnostic examinations that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

981. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

982. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

983. Plaintiffs' prescribing physicians would not have prescribed and/or recommended Ranitidine-Containing Products to Plaintiffs, would have changed the way in which they treated Plaintiffs' relevant conditions, changed the way they warned Plaintiffs about the signs and symptoms of serious adverse effects of Ranitidine-Containing Products, and discussed with

Plaintiffs the true risks of cancer, had Manufacturer Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of Ranitidine-Containing Products.

984. Upon information and belief, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of Ranitidine-Containing Products due to ranitidine's transformation into NDMA and, if they had been informed, would have used and prescribed alternative therapies to Plaintiffs.

985. Plaintiffs would not have used Ranitidine-Containing Products had Plaintiffs known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drugs.

VII. TOLLING / FRAUDULENT CONCEALMENT

986. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

987. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

988. The nature of Plaintiffs' injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims.

989. Plaintiffs bring this medical monitoring complaint within the applicable statute of

limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following Plaintiffs' awareness of their risk of injury and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know and had no reason to know of their injuries and/or the wrongful cause of those injuries.

990. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiffs and defects associated with Ranitidine-Containing Products as they transform into NDMA. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of ranitidine. As a result of Defendants' misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Plaintiffs had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

991. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which Defendants had exclusive control – and because Plaintiffs could not reasonably have known that Defendants' Ranitidine-Containing Products were defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

VIII. CLASS ALLEGATIONS

A. CLASS DEFINITIONS

992. Plaintiffs bring this action in their individual capacities and on behalf of their respective State Classes (described below), pursuant to Federal Rules of Civil Procedure 23(a),

(b)(2)-(3), and/or (c)(4).

1. Brand Manufacturer Prescription Medical Monitoring Class

GSK

993. Plaintiffs identified in the table below bring claims against Defendant GSK on behalf of themselves and their respective State GSK Prescription Medical Monitoring Class, each of which is defined as "All individuals who used GSK's prescription Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Alexander Monger	FL
Laura Monger	FL
Michael Tomlinson	FL
Teresa Dowler	IN
Alberta Griffin	MD
Ronda Lockett	MO
Michael Galloway	OH
Felicia Ball	PA

2. Brand Manufacturer OTC Medical Monitoring Classes

GSK

994. Plaintiffs identified in the table below bring claims against Defendant GSK on behalf of themselves and their respective State GSK OTC Medical Monitoring Class, each of which is defined as "All individuals who used GSK's OTC Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Richard Obrien	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Ricardo Moròn	FL
Ronald Ragis	FL
Charles Longfield	MD
Ronda Lockett	MO
Jonathan Ferguson	NV

Pfizer

995. Plaintiffs identified in the table below bring claims against Defendant Pfizer on behalf of themselves and their respective State Pfizer OTC Medical Monitoring Class, each of which is defined as "All individuals who used Pfizer's OTC Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Golbenaz Bakhtiar	CA
Richard Obrien	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Gustavo Velasquez	FL
Joshua Winans	FL
Ricardo Moròn	FL
Ronald Ragis	FL
Alberta Griffin	MD
Ida Adams	MD; WV
Charles Longfield	MD

Ronda Lockett	MO
Jonathan Ferguson	NV
Chris Troyan	OH
Michael Galloway	FL; OH

BI

996. Plaintiffs identified in the table below bring claims against Defendant BI on behalf of themselves and their respective State BI OTC Medical Monitoring Class, each of which is defined as "All individuals who used BI's OTC Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Richard Obrien	CA
Virginia Aragon	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Clifton McKinnon	FL
Gustavo Velasquez	FL
Jeannie Black	FL
Joshua Winans	FL
Marva Mccall	FL
Michael Tomlinson	FL
Ricardo Moròn	FL
Sharon Tweg	FL
Ronald Ragis	FL
Rebecca Sizemore	IN

Teresa Dowler	IN
Tracy Wells	IN
Charles Longfield	MD
Alberta Griffin	MD
Ida Adams	MD; WV
Antrenise Campbell	MO
Lorie Kendall-Songer	MO
Angel Vega	MT
Cesar Pinon	NV
Chris Troyan	OH
Michael Galloway	OH
Patricia Hess	OH
Teresa Waters	UT

Sanofi

997. Plaintiffs identified in the table below bring claims against Defendant Sanofi on behalf of themselves and their respective State Sanofi OTC Medical Monitoring Class, each of which is defined as "All individuals who used Sanofi's OTC Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Richard Obrien	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Gustavo Velasquez	FL
Jeannie Black	FL

Joshua Winans	FL
Michael Tomlinson	FL
Ricardo Moròn	FL
Sharon Tweg	FL
Sonia Diaz	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Alberta Griffin	MD
Ida Adams	MD
Lorie Kendall-Songer	MO
Chris Troyan	OH
Michael Galloway	OH
Teresa Waters	UT

3. Generic Prescription Medical Monitoring Classes

Amneal

998. Plaintiffs identified in the table below bring claims against Defendant Amneal on behalf of themselves and their respective State Amneal Prescription Medical Monitoring Class, each of which is defined as "All individuals who used Amneal's OTC Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Kevin Nelson	DC
Ana Pereira	FL

Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Joyce Taylor	FL
Alexander Monger	FL
Laura Monger	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH; FL
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

Dr. Reddy's

999. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's on behalf of themselves and their respective State Dr. Reddy's Prescription Medical Monitoring

Class, each of which is defined as "All individuals who used Dr. Reddy's prescription Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Antrenise Campbell	MO

Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

Glenmark

1000. Plaintiffs identified in the table below bring claims against Defendant Glenmark on behalf of themselves and their respective State Glenmark Prescription Medical Monitoring Class, each of which is defined as "All individuals who used Glenmark's prescription Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL

Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

Sandoz

1001. Plaintiffs identified in the table below bring claims against Defendant Sandoz on behalf of themselves and their respective State Sandoz Prescription Medical Monitoring Class, each of which is defined as "All individuals who used Sandoz's prescription Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Antrenise Campbell	MO
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO

Michael Galloway	OH; FL
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

Strides

1002. Plaintiffs identified in the table below bring claims against Defendant Strides on behalf of themselves and their respective State Strides Prescription Medical Monitoring Class, each of which is defined as "All individuals who used Strides' prescription Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL

Plaintiff Name	State of Usage
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

Teva

1003. Plaintiffs identified in the table below bring claims against Defendant Teva on behalf of themselves and their respective State Teva Prescription Medical Monitoring Class, each of which is defined as "All individuals who used Teva's prescription Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA

Plaintiff Name	**State of Usage**
Virginia Aragon	CA
Jeffrey Pisano	CO
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Joyce Taylor	FL
Alexander Monger	FL
Laura Monger	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Karen Foster	FL
Rebecca Sizemore	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Antrenise Campbell	MO
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH; FL
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Mynetta Hastings	WV

4. Store-Brand Medical Monitoring Classes

CVS

1004. Plaintiffs identified in the table below bring claims against Defendant CVS on behalf of themselves and their respective State CVS Medical Monitoring Class, each of which is defined as "All individuals who used CVS Health-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

Rite Aid

1005. Plaintiffs identified in the table below bring claims against Defendant Rite Aid on behalf of themselves and their respective State Rite Aid Medical Monitoring Class, each of which is defined as "All individuals who used Rite Aid-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

Walgreens

1006. Plaintiffs identified in the table below bring claims against Defendant Walgreens on behalf of themselves and their respective State Walgreens Medical Monitoring Class, each of which is defined as "All individuals who used Wal-Zan-branded Ranitidine-Containing Products

while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

Walmart

1007. Plaintiffs identified in the table below bring claims against Defendant Walmart on behalf of themselves and their respective State Walmart Medical Monitoring Class, each of which is defined as "All individuals who used Equate-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

5. Store-Brand Manufacturer Medical Monitoring Classes

Apotex

1008. Plaintiffs identified in the table below bring claims against Defendant Apotex on behalf of themselves and their respective State Apotex Rite Aid Medical Monitoring Class, each of which is defined as "All individuals who used Apotex's Rite Aid-branded Ranitidine-

Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

1009. Plaintiffs identified in the table below bring claims against Defendant Apotex on behalf of themselves and their respective State Apotex Wal-Zan Medical Monitoring Class, each of which is defined as "All individuals who used Apotex's Wal-Zan-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1010. Plaintiffs identified in the table below bring claims against Defendant Apotex on behalf of themselves and their respective State Apotex Equate Medical Monitoring Class, each of which is defined as "All individuals who used Apotex's Equate Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jeffrey Pisano	CO
Ronald Ragan	CO

Michael Tomlinson	FL
Mynetta Hastings	WV

Dr. Reddy's

1011. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's on behalf of themselves and their respective State Dr. Reddy's CVS Health Medical Monitoring Class, each of which is defined as "All individuals who used Dr. Reddy's CVS Health-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1012. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's on behalf of themselves and their respective State Dr. Reddy's Wal-Zan Medical Monitoring Class, each of which is defined as "All individuals who used Dr. Reddy's Wal-Zan-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO

Plaintiff Name	State of Usage
Ronald Ragan	CO
Ronald Ragis	FL

1013. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's on behalf of themselves and their respective State Dr. Reddy's Equate Medical Monitoring Class, each of which is defined as "All individuals who used Dr. Reddy's Equate-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

Perrigo

1014. Plaintiffs identified in the table below bring claims against Defendant Perrigo on behalf of themselves and their respective State Perrigo CVS Health Medical Monitoring Class, each of which is defined as "All individuals who used Perrigo's CVS Health-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Richard Obrien	CA
Rebecca Sizemore	IN

Plaintiff Name	State of Usage
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1015. Plaintiffs identified in the table below bring claims against Defendant Perrigo on behalf of themselves and their respective State Perrigo Rite Aid Medical Monitoring Class, each of which is defined as "All individuals who used Perrigo's Rite Aid-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Golbenaz Bakhtiar	CA
Richard Obrien	CA

1016. Plaintiffs identified in the table below bring claims against Defendant Perrigo on behalf of themselves and their respective State Perrigo Wal-Zan Medical Monitoring Class, each of which is defined as "All individuals who used Perrigo's Wal-Zan-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	State of Usage
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1017. Plaintiffs identified in the table below bring claims against Defendant Perrigo on behalf of themselves and their respective State Perrigo Equate Medical Monitoring Class, each of which is defined as "All individuals who used Perrigo's Equate-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

Strides

1018. Plaintiffs identified in the table below bring claims against Defendant Strides on behalf of themselves and their respective State Strides CVS Health Medical Monitoring Class, each of which is defined as "All individuals who used Strides' CVS Health-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State**
Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1019. Plaintiffs identified in the table below bring claims against Defendant Strides on behalf of themselves and their respective State Strides Rite Aid Medical Monitoring Class, each

of which is defined as "All individuals who used Strides' Rite Aid-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

1020. Plaintiffs identified in the table below bring claims against Defendant Strides on behalf of themselves and their respective State Strides Wal-Zan Medical Monitoring Class, each of which is defined as "All individuals who used Strides' Wal-Zan-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State**
Tangie Sims	AZ
Golbenaz Bakhitar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1021. Plaintiffs identified in the table below bring claims against Defendant Strides on behalf of themselves and their respective State Strides Equate Medical Monitoring Class, each of which is defined as "All individuals who used Strides' Equate-branded Ranitidine-Containing Products while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO

Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

* * *

1022. The aforementioned Classes may be collectively referred to as the "Classes" or "State Classes."

1023. Excluded from the State Classes are Defendants and any of their affiliates, parents, subsidiaries, officers, and directors; any entity in which Defendants have a controlling interest; all persons who make a timely election to be excluded from the class; governmental entities; and all judges assigned to hear any aspect of this litigation, including their immediate family members.

1024. Plaintiffs reserve the right to modify or amend the class definitions, including the addition of one or more subclasses, following discovery and prior to class certification.

B. FED. R. CIV. P. 23 REQUIREMENTS

1025. Each of the proposed State Classes meets the requirements of Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3) and/or 23(c)(4).

1026. ***Numerosity.*** The members of each State Class are so numerous that joinder is impracticable. Zantac has for decades been one of the most popular medications for relief of heartburn, acid reflux, and similar conditions and, thus, it is reasonable to infer that each State Class includes thousands of members who are geographically dispersed.

1027. ***Typicality.*** Plaintiffs' claims are typical of the claims of putative State Class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the claims of the other State Class members. Each Plaintiff, like each State Class member, took prescription and/or OTC Ranitidine-Containing Products, including Zantac, manufactured or sold

by Defendants, which are not safe for human consumption and, thus, Plaintiffs, like each State Class member, face an increased risk of developing any of the Subject Cancers. Plaintiffs, like each State Class member, were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the State Class members.

1028. ***Adequacy.*** Plaintiffs will fairly and adequately protect the interests of the State Class members. Plaintiffs' interests and the interests of all other members of each respective State Class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the State Class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

1029. ***Commonality and Predominance.*** There are numerous questions of law and fact common to the State Classes, and these common questions predominate over any issues affecting only individual State Class members. Questions common to the State Classes include, but are not limited to, the following:

(a) whether Zantac and other Ranitidine-Containing Products contain, are likely to contain, or exposed State Class members to, unacceptable levels of NDMA;

(b) whether consumption of Zantac and other Ranitidine-Containing Products increases the risk of developing any of the Subject Cancers;

(c) whether Defendants knew or should have known that Zantac and other Ranitidine-Containing Products contain, or are likely to contain, unacceptable levels of NDMA;

(d) whether Defendants knew or should have known that consumption of Zantac and other Ranitidine-Containing Products increased the risk of developing any of the Subject Cancers;

(e) whether Defendants acted to conceal the fact that Zantac and other Ranitidine-Containing Products expose users to unacceptable quantities of NDMA;

(f) whether Defendants acted to conceal the fact that consumption of Zantac and other Ranitidine-Containing Products, including Zantac, increased the risk of developing cancer;

(g) whether Brand Manufacturer Defendants' warnings regarding the risks of cancer were adequate;

(h) whether Defendants had a duty to, and failed to, timely, adequately, and appropriately report adverse events and other appropriate information to the FDA;

(i) whether Defendants failed to warn consumers regarding the appropriate expiration dates for Zantac and other Ranitidine-Containing Products;

(j) whether Defendants were negligent in labeling, packaging, marketing, advertising, promoting and/or manufacturing and/or selling Zantac and other Ranitidine-Containing Products;

(k) whether Defendants were negligent in labeling, packaging, marketing, advertising, and/or promoting Zantac and other Ranitidine-Containing Products and their safety when used within the expiration dates;

(l) whether Defendants' labeling, packaging, marketing, advertising, and/or promoting Zantac and other Ranitidine-Containing Products and their safety when used beyond the expiration dates;

(m) whether Defendants were negligent in their storage and/or transportation of Zantac and other Ranitidine-Containing Products;

(n) whether Defendants are liable for failing to warn of the risks associated with use of Zantac and other Ranitidine-Containing Products;

(o) whether Plaintiffs and State Class members are entitled to medical monitoring relief as a result of their increased risk of developing the Subject Cancers based on use of Zantac and other Ranitidine-Containing Products; and

(p) the type and format of medical monitoring relief, declaratory relief and/or injunctive relief that is appropriate.

1030. ***Superiority.*** A class action is superior to other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not

be sufficient to justify individual litigation. Here, the damages suffered by Plaintiffs and the State Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendants, and thus, individual litigation to redress Defendants' wrongful conduct would be impracticable. Individual litigation by each State Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

1031. ***Injunctive and Declaratory Relief.*** Class certification is also appropriate under Rule 23(b)(2) because Defendants acted and refused to act on grounds generally applicable to the State Class as a whole, such that final declaratory and/or injunctive relief is appropriate with respect to the State Class as a whole. Such declaratory and/or injunctive relief includes, but is not limited to, implementation and funding of a medical monitoring program for Plaintiffs and State Class members that is sufficient to monitor their health and ensure the early detection and diagnosis of diseases, specifically the Subject Cancers.

1032. Plaintiffs reserve the right to seek certification of Rule 23(c)(4) of common questions related to Defendants' knowledge, conduct, products, and duties.

IX. CAUSES OF ACTION

A. CAUSES OF ACTION AGAINST DEFENDANT GSK WITH RESPECT TO PRESCRIPTION ZANTAC

1033. Plaintiffs identified in the table below bring claims against Defendant GSK with respect to prescription Zantac on behalf of themselves and their respective State GSK Prescription Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff

incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Alexander Monger	FL
Laura Monger	FL
Michael Tomlinson	FL
Teresa Dowler	IN
Alberta Griffin	MD
Ronda Lockett	MO
Michael Galloway	OH
Felicia Ball	PA

1. California

COUNT 1:
Negligence – Failure to Warn Through Warnings and Precautions – California

1034. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1035. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1036. The allegations in this Count apply to GSK during the time periods in which it was manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in paragraphs 152-71, which are incorporated by reference.

1037. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1038. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

1039. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1040. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1041. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

1042. The latent injuries from which Plaintiff and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1043. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1044. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1045. By monitoring and testing Plaintiffs, the risk that Plaintiff and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1046. Plaintiff and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1047. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1048. Plaintiff and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 2:
Negligence – Failure to Warn Through Proper Expiration Dates – California

1049. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1050. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1051. The allegations in this Count apply to GSK during the time periods in which it was manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in paragraphs 152-71, which are incorporated by reference.

1052. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1053. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

1054. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1055. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1056. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1057. The latent injuries from which Plaintiffs and the California GSK Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1058. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1059. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1060. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1061. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1062. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1063. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 3:
Strict Liability – Failure to Warn Consumers Through The FDA – California

1064. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1065. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1066. The allegations in this Count apply to GSK during the time periods in which it was

manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in paragraphs 152-71, which are incorporated by reference.

1067. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1068. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

1069. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

1070. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1071. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. §314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

1072. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

1073. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1074. The latent injuries from which Plaintiffs and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1075. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1076. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1077. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK

Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1078. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1079. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1080. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 4:
Negligent Product Containers – California

1081. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1082. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1083. The allegations in this Count apply to GSK during the time periods in which it was manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in paragraphs 152-71, which are incorporated by reference.

1084. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1085. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1086. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1087. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1088. The latent injuries from which Plaintiffs and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1089. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1090. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1091. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1092. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1093. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1094. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 5:
Negligent Storage and Transportation – California

1095. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1096. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1097. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1098. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1099. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

1100. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1101. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1102. The latent injuries from which Plaintiffs and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1103. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1104. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1105. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1106. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1107. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1108. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Colorado

COUNT 6:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Colorado

1109. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1110. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1111. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1112. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1113. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

1114. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

1115. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1116. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1117. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1118. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

1119. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1120. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1121. By monitoring and testing Plaintiffs, the risk Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1122. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1123. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1124. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a Court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 7:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Colorado

1125. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1126. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1127. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1128. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1129. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1130. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

1131. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1132. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1133. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1134. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1135. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1136. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1137. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1138. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1139. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1140. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 8:
Medical Monitoring – Negligent Product Containers – Colorado

1141. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1142. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1143. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1144. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1145. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased

their risk of developing various types of serious and potentially fatal Subject Cancers.

1146. Under Colorado law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1147. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1148. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1149. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1150. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1151. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1152. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1153. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1154. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1155. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 9:
Medical Monitoring – Negligent Storage and Transportation – Colorado

1156. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1157. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1158. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1159. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1160. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1161. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1162. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1163. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1164. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1165. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1166. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1167. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1168. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1169. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1170. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Florida

COUNT 10:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Florida

1171. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–-4 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1172. This cause of action is brought by Michael Galloway, Alexander Monger, Laura Monger, and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1173. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1174. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1175. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1176. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1177. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1178. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1179. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1180. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1181. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1182. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1183. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK

Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1184. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1185. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1186. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 11:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Florida

1187. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1188. This cause of action is brought by Michael Galloway, Alexander Monger, Laura Monger, and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1189. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1190. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1191. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1192. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1193. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1194. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1195. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1196. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1197. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1198. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1199. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1200. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1201. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1202. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 12:
Medical Monitoring – Negligent Product Containers – Florida

1203. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1204. This cause of action is brought by Michael Galloway and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1205. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1206. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1207. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1208. Under Florida law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1209. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1210. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused

Plaintiffs' injuries.

1211. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1212. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1213. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1214. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1215. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1216. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members

seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1217. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1218. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 13:
Medical Monitoring – Negligent Storage and Transportation – Florida

1219. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1220. This cause of action is brought by Michael Galloway, Alexander Monger, Laura Monger, and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1221. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1222. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1223. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1224. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1225. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1226. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have

suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1227. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1228. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1229. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1230. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1231. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical

Monitoring Class members as frequently and appropriately as necessary.

1232. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1233. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Indiana

COUNT 14:
Negligence – Failure to Warn Through Warnings and Precautions – Indiana

1234. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1235. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1236. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1237. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1238. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

1239. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Productwere unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1240. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1241. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

1242. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1243. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1244. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1245. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1246. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1247. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1248. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 15:
Negligence – Failure To Warn Through Proper Expiration Dates – Indiana

1249. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1250. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"),

against GSK (for the purposes of this Count, "Defendant").

1251. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1252. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1253. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

1254. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1255. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1256. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1257. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1258. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1259. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1260. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1261. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1262. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1263. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 16:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

1264. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1265. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1266. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1267. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1268. Under Indiana law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

1269. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

1270. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1271. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. §314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

1272. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks

that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

1273. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1274. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1275. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1276. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1277. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1278. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1279. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1280. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 17:
Negligent Product Containers – Indiana

1281. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1282. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1283. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1284. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1285. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1286. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1287. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1288. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1289. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1290. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1291. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1292. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1293. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1294. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 18:
Negligent Storage and Transportation – Indiana

1295. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1296. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1297. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

1298. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1299. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

1300. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1301. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1302. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1303. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

1304. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1305. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1306. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1307. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1308. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Maryland

COUNT 19:
Negligence – Failure to Warn Through Warnings and Precautions – Maryland

1309. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1310. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1311. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1312. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1313. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

1314. Defendant breached this duty for its Ranitidine-Containing Products. The warnings

included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1315. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1316. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1317. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1318. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1319. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1320. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1321. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1322. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1323. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue

to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 20:
Negligence – Failure To Warn Through Proper Expiration Dates – Maryland

1324. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1325. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1326. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1327. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1328. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

1329. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1330. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1331. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1332. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1333. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1334. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1335. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK

Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1336. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1337. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1338. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 21:
Negligence – Failure To Warn Consumers Through the FDA – Maryland

1339. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1340. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1341. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1342. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1343. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

1344. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like

Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

1345. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1346. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendants failed to warn anyone through any medium.

1347. Specifically, Defendants failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

1348. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1349. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1350. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1351. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1352. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1353. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1354. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1355. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 22:
Negligent Product Containers – Maryland

1356. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1357. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1358. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1359. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1360. Under Maryland law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1361. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1362. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1363. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1364. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

1365. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1366. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1367. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1368. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1369. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 23:
Negligent Storage and Transportation – Maryland

1370. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1371. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1372. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1373. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1374. Under Maryland law, Defendant had a duty to exercise reasonable care in transporting and storing products.

1375. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

1376. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, transported, and, therefore, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1377. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1378. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1379. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1380. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1381. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1382. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1383. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Missouri

COUNT 24:
Negligence – Failure to Warn Through Warnings and Precautions – Missouri

1384. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1385. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1386. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1387. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1388. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1389. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1390. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

1391. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1392. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1393. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1394. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1395. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1396. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members

seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1397. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1398. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 25:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

1399. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1400. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1401. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1402. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1403. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1404. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1405. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1406. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1407. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1408. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1409. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1410. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1411. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical

Monitoring Class members as frequently and appropriately as necessary.

1412. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1413. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 26:
Strict Liability – Failure to Warn Consumers Through the FDA – Missouri

1414. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1415. This cause of action is brought by Ronda Lockett, individually and on behalf of the

Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1416. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1417. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1418. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

1419. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers, such as Defendant, have a state law duty to do so.

1420. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1421. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant,

had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

1422. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

1423. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1424. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1425. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1426. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1427. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1428. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1429. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1430. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 27: Negligent Product Containers – Missouri

1431. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1432. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1433. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1434. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1435. Under Missouri law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1436. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1437. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have

sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1438. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1439. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1440. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1441. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1442. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1443. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1444. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 28: Negligent Storage and Transportation – Missouri

1445. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1446. This cause of action is brought by Ronda Lockett, individually and on behalf of the

Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1447. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1448. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1449. Under Missouri law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1450. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1451. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1452. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

1453. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1454. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1455. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1456. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1457. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1458. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Ohio

COUNT 29:
Strict Liability – Failure to Warn Through Warnings and Precautions – Ohio

1459. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1460. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1461. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1462. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-

Specific Allegations) as to GSK.

1463. Under Ohio law, a manufacturer, like Defedant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

1464. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1465. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1466. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1467. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

1468. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1469. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1470. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1471. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1472. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1473. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 30:
Strict Liability – Failure To Warn Through Proper Expiration Dates – Ohio

1474. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1475. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1476. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1477. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1478. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

1479. Defendant breached this duty for the Ranitidine-Containing it manufactured. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1480. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1481. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1482. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1483. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1484. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1485. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1486. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1487. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1488. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 31:
Negligent Product Containers – Ohio

1489. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1490. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1491. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1492. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1493. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1494. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1495. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

1496. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1497. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1498. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1499. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1500. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1501. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1502. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1503. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 32:
Negligent Storage and Transportation – Ohio

1504. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1505. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1506. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1507. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1508. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

1509. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1510. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class

members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1511. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1512. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1513. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1514. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1515. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1516. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1517. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Pennsylvania

COUNT 33:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – Pennsylvania

1518. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully

stated herein.

1519. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1520. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1521. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1522. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1523. Under Pennsylvania law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning.

1524. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1525. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1526. As a direct and proximate result of Defendant's failure to provide adequate

warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1527. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1528. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1529. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1530. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1531. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1532. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1533. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 34:
Medical Monitoring – Negligent Failure to Warn Through Proper Expiration Dates – Pennsylvania

1534. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully

stated herein.

1535. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1536. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1537. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1538. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject CancersRanitidine-Containing Products").

1539. Under Pennsylvania law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning.

1540. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1541. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1542. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Pennsylvania GSK

Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1543. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1544. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1545. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1546. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1547. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1548. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1549. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 35:
Medical Monitoring – Negligent Failure to Warn Consumers Through the FDA – Pennsylvania

1550. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1551. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1552. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1553. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1554. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1555. Pennsylvania law "may impose liability for the failure to report to the FDA. …the duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiffs has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

1556. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor,

manufacturers, like Defendant, have a state law duty to do so.

1557. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1558. Under federal regulations, Brand Manufacturers, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. Brand Manufacturers, like Defendant, were also required to warn consumers through a warning to FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

1559. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

1560. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1561. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1562. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1563. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1564. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1565. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1566. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that

they may require frequent medical monitoring for the purpose of diagnosis.

1567. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 36:
Medical Monitoring – Negligent Product Containers – Pennsylvania

1568. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1569. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1570. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1571. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to GSK.

1572. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1573. Under Pennsylvania law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1574. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1575. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1576. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1577. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1578. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1579. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1580. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1581. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1582. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 37:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

1583. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1584. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1585. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1586. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1587. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1588. Under Pennsylvania law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1589. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

1590. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1591. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1592. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1593. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1594. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1595. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

1596. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1597. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

B. CAUSES OF ACTION AGAINST DEFENDANT GSK WITH RESPECT TO OTC ZANTAC

1598. Plaintiffs identified in the table below bring claims against Defendant GSK with respect to OTC Zantac on behalf of themselves and their respective State GSK OTC Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by

reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Ricardo Moròn	FL
Ronald Ragis	FL
Charles Longfield	MD
Ronda Lockett	MO
Jonathan Ferguson	NV

1. California

COUNT 38:
Negligence – Failure to Warn Through Warnings and Precautions – California

1599. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1600. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1601. The allegations in this Count apply to GSK during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1602. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1603. Under California law, manufacturers, like Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

1604. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1605. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1606. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1607. The latent injuries from which Plaintiffs and the California GSK OTC Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1608. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1609. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1610. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1611. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1612. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1613. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 39:
Negligence – Failure to Warn Through Proper Expiration Dates – California

1614. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1615. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1616. The allegations in this Count apply to GSK during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1617. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1618. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

1619. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1620. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1621. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1622. The latent injuries from which Plaintiffs and the California GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1623. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1624. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1625. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1626. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1627. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1628. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 40:
Strict Liability – Failure to Warn Consumers Through the FDA – California

1629. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1630. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1631. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1632. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1633. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

1634. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

1635. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1636. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. § 314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

1637. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks

that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

1638. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1639. The latent injuries from which Plaintiffs and the California GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1640. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1641. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1642. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1643. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1644. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1645. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 41:
Negligent Product Containers – California

1646. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1647. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1648. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1649. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1650. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1651. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1652. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1653. The latent injuries from which Plaintiffs and the California GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1654. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1655. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1656. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1657. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1658. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1659. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 42:
Negligent Storage and Transportation – California

1660. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1661. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1662. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

1663. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1664. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

1665. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1666. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1667. The latent injuries from which Plaintiffs and the California GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1668. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

1669. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1670. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1671. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1672. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1673. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Colorado

COUNT 43:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – Colorado

1674. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1675. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1676. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1677. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1678. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1679. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care

to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

1680. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1681. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1682. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1683. The latent injuries from which Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1684. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1685. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1686. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1687. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1688. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1689. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 44:
Medical Monitoring – Negligent Failure to Warn Through Proper Expiration Dates – Colorado

1690. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1691. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1692. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1693. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1694. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1695. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

1696. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1697. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1698. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1699. The latent injuries from which Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1700. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1701. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1702. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1703. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1704. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1705. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 45: Medical Monitoring – Negligent Product Containers – Colorado

1706. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1707. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1708. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1709. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1710. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1711. Under Colorado law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1712. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1713. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1714. The latent injuries from which Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1715. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1716. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1717. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1718. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1719. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1720. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 46:
Medical Monitoring – Negligent Storage and Transportation – Colorado

1721. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1722. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1723. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1724. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1725. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

1726. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1727. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1728. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal

Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1729. The latent injuries from which Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1730. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1731. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1732. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1733. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK OTC Medical

Monitoring Class members as frequently and appropriately as necessary.

1734. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1735. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Florida

COUNT 47:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – Florida

1736. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1737. This cause of action is brought by Michael Galloway, Ricardo Moron and Ronald Ragis, individually and on behalf of the Florida GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1738. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1739. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1740. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1741. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1742. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1743. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1744. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1745. The latent injuries from which Plaintiffs and the Florida GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1746. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1747. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1748. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1749. Plaintiffs and the Florida GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1750. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1751. Plaintiffs and the Florida GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 48:
Medical Monitoring – Negligent Failure to Warn Through Proper Expiration Dates – Florida

1752. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing

GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1753. This cause of action is brought by Michael Galloway, Ricardo Moron and Ronald Ragis, individually and on behalf of the Florida GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1754. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1755. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1756. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1757. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1758. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1759. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1760. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1761. The latent injuries from which Plaintiffs and the Florida GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1762. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1763. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1764. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1765. Plaintiffs and the Florida GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1766. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1767. Plaintiffs and the Florida GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 49:
Medical Monitoring – Negligent Product Containers – Florida

1768. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing

GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1769. This cause of action is brought by Michael Galloway, Ricardo Moron and Ronald Ragis, individually and on behalf of the Florida GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1770. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1771. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1772. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1773. Under Florida law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1774. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1775. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and Florida GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1776. The latent injuries from which Plaintiffs and the Florida GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1777. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1778. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1779. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1780. Plaintiffs and the Florida GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1781. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1782. Plaintiffs and the Florida GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 50:
Medical Monitoring – Negligent Storage and Transportation – Florida

1783. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1784. This cause of action is brought by Michael Galloway, Ricardo Moron and Ronald Ragis, individually and on behalf of the Florida GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1785. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

1786. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1787. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

1788. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1789. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1790. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, transported, and sold, and, therefore, Plaintiffs and Florida GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1791. The latent injuries from which Plaintiffs and the Florida GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1792. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1793. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1794. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1795. Plaintiffs and the Florida GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1796. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1797. Plaintiffs and the Florida GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-

approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Maryland

COUNT _51:
Negligence – Failure to Warn Through Warnings and Precautions – Maryland

1798. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1799. This cause of action is brought by Charles Longfield, individually and on behalf of the Maryland GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1800. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1801. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1802. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

1803. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1804. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1805. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Maryland GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1806. The latent injuries from which Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1807. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

1808. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1809. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1810. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1811. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1812. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 52:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

1813. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1814. This cause of action is brought by Charles Longfield, individually and on behalf of the Maryland GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1815. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1816. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1817. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

1818. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1819. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1820. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1821. The latent injuries from which Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1822. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1823. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1824. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1825. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1826. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1827. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 53:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

1828. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1829. This cause of action is brought by Charles Longfield, individually and on behalf of the Maryland GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1830. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1831. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1832. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

1833. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the

FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

1834. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1835. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendants failed to warn anyone through any medium.

1836. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

1837. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses

and expenses associated with ongoing medical monitoring.

1838. The latent injuries from which Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1839. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1840. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1841. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1842. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1843. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1844. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 54:
Negligent Product Containers – Maryland

1845. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1846. This cause of action is brought by Charles Longfield, individually and on behalf of the Maryland GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"),

against GSK (for the purposes of this Count, "Defendant").

1847. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1848. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1849. Under Maryland law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1850. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1851. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and Maryland GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1852. The latent injuries from which Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1853. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1854. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1855. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1856. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1857. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1858. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 55:
Negligent Storage and Transportation – Maryland

1859. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1860. This cause of action is brought by Charles Longfield, individually and on behalf of the Maryland GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1861. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1862. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1863. Under Maryland law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1864. Defendant breached this duty by failing to implement or enforce policies to ensure

Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1865. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and Maryland GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1866. The latent injuries from which Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1867. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1868. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1869. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

1870. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1871. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1872. Plaintiffs and the Maryland GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Missouri

COUNT 56:
Negligence – Failure to Warn Through Warnings and Precautions – Missouri

1873. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1874. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1875. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1876. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1877. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1878. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1879. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1880. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1881. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1882. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1883. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1884. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1885. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1886. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1887. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 57:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

1888. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1889. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1890. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1891. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1892. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1893. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1894. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1895. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK OTC

Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1896. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1897. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1898. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1899. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1900. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1901. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1902. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 58:
Strict Liability – Failure to Warn Consumers Through the FDA – Missouri

1903. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1904. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1905. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1906. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1907. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

1908. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers, such as Defendant, have a state law duty to do so.

1909. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1910. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers

was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

1911. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

1912. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1913. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1914. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1915. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1916. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1917. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1918. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1919. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face

an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 59:
Negligent Product Containers – Missouri

1920. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1921. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1922. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1923. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1924. Under Missouri law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

1925. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

1926. As a direct and proximate result of this failure, excessive levels of NDMA built up

in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1927. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1928. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1929. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1930. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1931. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1932. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1933. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 60:
Negligent Storage and Transportation – Missouri

1934. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing

GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1935. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1936. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1937. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

1938. Under Missouri law, Defendant has a duty to exercise reasonable care in transporting and storing products.

1939. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

1940. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1941. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1942. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1943. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1944. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1945. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1946. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1947. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Nevada

COUNT 61:
Negligence – Failure to Warn Through Warnings and Precautions – Nevada

1948. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1949. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1950. The allegations in this Count apply to GSK during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1951. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to GSK.

1952. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1953. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1954. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1955. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1956. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1957. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1958. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1959. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1960. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1961. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1962. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 62:
Negligence – Failure to Warn Through Proper Expiration Dates – Nevada

1963. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1964. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1965. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1966. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to GSK.

1967. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1968. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1969. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1970. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1971. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1972. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1973. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1974. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1975. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1976. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1977. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term

physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 63:
Negligence – Failure to Warn Consumers Through the FDA – Nevada

1978. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1979. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1980. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1981. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to GSK.

1982. "Nevada law contains a parallel requirement [to federal law] because it imposes a continuing duty on manufacturers to warn of defects in their products." *Scovil v. Medtronic Inc.*,

No. 2:14-CV-00213-APG, 2015 WL 880614, at *7 (D. Nev. Mar. 2, 2015); *see also Forest v. E.I. DuPont de Nemours & Co.*, 791 F. Supp. 1460, 1464 (D. Nev. 1992) (discussing Restatement (Second) § 388 and explaining that at the summary judgment stage, "negligence and strict liability claims should be considered together" and that on failure to warn the "Nevada formulation is based on California common law").

1983. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

1984. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

1985. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

1986. Specifically, Defendants failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This

failure breached their duty of reasonable care.

1987. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1988. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1989. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1990. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1991. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1992. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek

creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1993. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1994. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 64:
Negligent Product Containers – Nevada

1995. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1996. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1997. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

1998. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to GSK.

1999. Under Nevada law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2000. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2001. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products each Manufacturer Defendant sold, and, therefore, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2002. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2003. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2004. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2005. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2006. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2007. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2008. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 65:
Negligent Storage and Transportation – Nevada

2009. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 360-83 (describing GSK's failure to warn), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2010. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

2011. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2012. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to GSK.

2013. Under Nevada law, Defendant, has a duty to exercise reasonable care in transporting and storing products.

2014. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2015. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2016. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2017. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2018. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2019. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2020. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2021. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2022. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an

unreasonable risk of injury and disability and remain undiagnosed.

C. CAUSES OF ACTION AGAINST DEFENDANT PFIZER WITH RESPECT TO OTC ZANTAC

2023. Plaintiffs identified in the table below bring claims against Defendant Pfizer with respect to prescription Zantac on behalf of themselves and their respective State Pfizer OTC Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Richard Obrien	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Gustavo Velasquez	FL
Joshua Winans	FL
Ricardo Moròn	FL
Ronald Ragis	FL
Alberta Griffin	MD
Ida Adams	MD; WV
Charles Longfield	MD
Ronda Lockett	MO
Jonathan Ferguson	NV
Chris Troyan	OH
Michael Galloway	FL; OH

1. California

COUNT 66:
Negligence – Failure to Warn Through Warnings and Precautions – California

2024. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2025. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2026. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2027. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2028. Under California law, manufacturers, like Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

2029. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under

hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2030. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2031. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and California Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2032. The latent injuries from which Plaintiffs and the California Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2033. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2034. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2035. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2036. Plaintiffs and the California Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2037. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2038. Plaintiffs and the California Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the California Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 67:
Negligence – Failure to Warn Through Proper Expiration Dates – California

2039. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2040. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2041. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2042. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2043. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

2044. Defendant breached this duty for its Ranitidine-Containing Products. The

expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2045. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2046. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2047. The latent injuries from which Plaintiffs and the California Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2048. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2049. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2050. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2051. Plaintiffs and the California Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2052. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2053. Plaintiffs and the California Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 68:
Strict Liability – Failure to Warn Consumers Through the FDA – California

2054. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2055. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2056. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2057. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Pfizer.

2058. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

2059. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

2060. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2061. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. § 314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

2062. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

2063. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2064. The latent injuries from which Plaintiffs and the California Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2065. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2066. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2067. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2068. Plaintiffs and the California Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2069. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2070. Plaintiffs and the California Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 69:
Negligent Product Containers – California

2071. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2072. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count,

"Defendant").

2073. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2074. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2075. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2076. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2077. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2078. The latent injuries from which Plaintiffs and the California Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2079. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2080. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2081. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2082. Plaintiffs and the California Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2083. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2084. Plaintiffs and the California Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 70:
Negligent Storage and Transportation – California

2085. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2086. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2087. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2088. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2089. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

2090. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2091. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and California Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2092. The latent injuries from which Plaintiffs and the California Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2093. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2094. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2095. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Pfizer

OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2096. Plaintiffs and the California Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2097. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2098. Plaintiffs and the California Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Colorado

COUNT 71:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Colorado

2099. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2100. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2101. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2102. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2103. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2104. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

2105. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under

hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2106. Plaintiff or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2107. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiff and Colorado Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2108. The latent injuries from which Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2109. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2110. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2111. By monitoring and testing Plaintiff, the risk that Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2112. Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2113. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2114. Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the Colorado Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 72:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Colorado

2115. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2116. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2117. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2118. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2119. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2120. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

2121. Defendant breached this duty for its Ranitidine-Containing Products. The

expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2122. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2123. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2124. The latent injuries from which Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2125. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2126. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2127. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2128. Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2129. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2130. Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 73:
Medical Monitoring – Negligent Product Containers – Colorado

2131. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2132. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2133. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2134. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2135. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2136. Under Colorado law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2137. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2138. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Colorado Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2139. The latent injuries from which Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2140. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2141. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2142. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2143. Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2144. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2145. Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 74:
Medical Monitoring – Negligent Storage And Transportation – Colorado

2146. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing

Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2147. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2148. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2149. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2150. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2151. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2152. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2153. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Colorado Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2154. The latent injuries from which Plaintiffs and the Colorado Pfizer OTC Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2155. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2156. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2157. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2158. Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2159. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2160. Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Florida

COUNT 75:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Florida

2161. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2162. This cause of action is brought by Gustavo Velasquez, Joshua Winans, Ricardo Moron, Michael Galloway, and Ronald Ragis, individually and on behalf of the Florida Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for

the purposes of this Count, "Defendant").

2163. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2164. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2165. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2166. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

2167. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2168. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2169. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida Pfizer OTC Medical

Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2170. The latent injuries from which Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2171. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2172. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2173. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2174. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2175. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2176. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 76:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Florida

2177. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2178. This cause of action is brought by Gustavo Velasquez, Joshua Winans, Ricardo Moron, Michael Galloway, and Ronald Ragis, individually and on behalf of the Florida Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2179. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2180. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2181. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2182. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

2183. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2184. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2185. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2186. The latent injuries from which Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2187. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2188. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2189. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2190. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2191. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2192. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 77:
Medical Monitoring – Negligent Product Containers – Florida

2193. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine

and injury), as if fully stated herein.

2194. This cause of action is brought by Gustavo Velasquez, Joshua Winans, Ricardo Moron, Michael Galloway, and Ronald Ragis, individually and on behalf of the Florida Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2195. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2196. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2197. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2198. Under Florida law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2199. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2200. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

2201. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses

associated with ongoing medical monitoring.

2202. The latent injuries from which Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2203. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2204. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2205. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2206. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2207. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2208. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 78:
Medical Monitoring – Negligent Storage and Transportation – Florida

2209. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2210. This cause of action is brought by Gustavo Velasquez, Joshua Winans, Ricardo Moron, Michael Galloway, and Ronald Ragis, individually and on behalf of the Florida Pfizer

OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2211. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2212. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2213. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2214. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2215. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2216. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2217. The latent injuries from which Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2218. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2219. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2220. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2221. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2222. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Pfizer OTC Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

2223. Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Maryland

COUNT 79:
Negligence – Failure to Warn Through Warnings and Precautions – Maryland

2224. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2225. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2226. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2227. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2228. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

2229. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2230. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2231. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Maryland Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2232. The latent injuries from which Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

2233. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2234. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2235. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2236. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2237. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2238. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 80:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

2239. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2240. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2241. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2242. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2243. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

2244. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2245. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2246. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2247. The latent injuries from which Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2248. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

2249. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2250. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2251. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2252. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2253. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 81:
Negligence – Failure to Warn Consumers Through the FDA– Maryland

2254. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2255. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2256. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2257. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Pfizer

2258. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an

effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

2259. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

2260. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2261. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendants failed to warn anyone through any medium.

2262. Specifically, Defendants failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

2263. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2264. The latent injuries from which Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2265. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2266. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2267. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2268. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2269. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2270. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 82:
Negligent Product Containers– Maryland

2271. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing

Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2272. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2273. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2274. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2275. Under Maryland law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2276. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2277. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2278. The latent injuries from which Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2279. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2280. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2281. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2282. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2283. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Pfizer OTC Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

2284. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 83:
Negligent Storage and Transportation – Maryland

2285. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2286. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2287. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2288. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-

Specific Allegations) as to Pfizer.

2289. Under Maryland law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2290. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2291. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Maryland Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2292. The latent injuries from which Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2293. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2294. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2295. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2296. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2297. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2298. Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Missouri

COUNT 84:
Negligence – Failure to Warn Through Warnings and Precautions – Missouri

2299. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2300. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2301. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2302. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2303. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

2304. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under

hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2305. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2306. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2307. The latent injuries from which Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2308. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2309. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2310. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2311. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2312. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2313. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 85:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

2314. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2315. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2316. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2317. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2318. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

2319. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2320. Plaintiffs or their doctors would have read and heeded these warnings had they been

included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2321. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2322. The latent injuries from which Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2323. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2324. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2325. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

2326. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2327. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2328. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 86:
Strict Liability – Failure to Warn Consumers Through the FDA – Missouri

2329. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2330. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2331. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2332. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Pfizer

2333. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

2334. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers, such as Defendant, have a state law duty to do so.

2335. The FDA was reasonably expected to disseminate this information. No speculation

is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2336. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

2337. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

2338. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2339. The latent injuries from which Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

2340. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2341. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2342. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2343. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2344. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2345. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 87:
Negligent Product Containers – Missouri

2346. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2347. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2348. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2349. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2350. Under Missouri law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2351. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2352. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2353. The latent injuries from which Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2354. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2355. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2356. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2357. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2358. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2359. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 88:
Negligent Storage and Transportation – Missouri

2360. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2361. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2362. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2363. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2364. Under Missouri law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2365. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2366. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class

members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2367. The latent injuries from which Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2368. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2369. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2370. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2371. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2372. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2373. Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Nevada

COUNT 89:
Negligence – Failure to Warn Through Warnings and Precautions – Nevada

2374. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine

and injury), as if fully stated herein.

2375. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2376. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2377. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2378. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

2379. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2380. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2381. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing

serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2382. The latent injuries from which Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2383. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2384. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2385. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2386. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring

Class members as frequently and appropriately as necessary.

2387. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2388. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 90:
Negligence – Failure to Warn Through Proper Expiration Dates – Nevada

2389. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2390. This cause of action is brought by Jonathan Ferguson, individually and on behalf

of the Nevada Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2391. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2392. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2393. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

2394. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2395. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2396. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2397. The latent injuries from which Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2398. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2399. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2400. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2401. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2402. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2403. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 91:
Negligence – Failure to Warn Consumers Through the FDA – Nevada

2404. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2405. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2406. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

2407. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Pfizer

2408. "Nevada law contains a parallel requirement [to federal law] because it imposes a continuing duty on manufacturers to warn of defects in their products." *Scovil v. Medtronic Inc.*, No. 2:14-CV-00213-APG, 2015 WL 880614, at *7 (D. Nev. Mar. 2, 2015); *see also Forest v. E.I. DuPont de Nemours & Co.*, 791 F. Supp. 1460, 1464 (D. Nev. 1992) (discussing Restatement (Second) § 388 and explaining that at the summary judgment stage, "negligence and strict liability claims should be considered together" and that on failure to warn the "Nevada formulation is based on California common law").

2409. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

2410. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2411. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public.

Brand Manufacturer Defendants failed to warn anyone through any medium.

2412. Specifically, Defendants failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

2413. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2414. The latent injuries from which Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2415. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2416. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2417. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2418. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2419. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2420. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 92:
Negligent Product Containers – Nevada

2421. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2422. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2423. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2424. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2425. Under Nevada law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2426. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2427. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products each Manufacturer Defendant sold, and, therefore, Plaintiffs

and the Nevada Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2428. The latent injuries from which Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2429. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2430. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2431. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2432. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2433. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2434. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 93:
Negligent Storage and Transportation – Nevada

2435. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2436. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2437. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2438. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2439. Under Nevada law, Defendant, has a duty to exercise reasonable care in transporting and storing products.

2440. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2441. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2442. The latent injuries from which Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2443. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2444. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2445. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2446. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2447. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada Pfizer OTC Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

2448. Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Ohio

COUNT 94:
Strict Liability – Failure to Warn Through Warnings and Precautions – Ohio

2449. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2450. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2451. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2452. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2453. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

2454. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2455. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2456. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Ohio Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2457. The latent injuries from which Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2458. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2459. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2460. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2461. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2462. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Pfizer OTC Medical Monitoring Class members in writing that they may require

frequent medical monitoring for the purpose of diagnosis.

2463. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 95:
Strict Liability – Failure to Warn Through Proper Expiration Dates – Ohio

2464. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2465. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2466. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2467. Plaintiffs incorporate herein Paragraphs 880-906 (Additional Count-Specific

Allegations) as to Pfizer.

2468. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

2469. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2470. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2471. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2472. The latent injuries from which Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2473. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2474. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2475. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2476. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2477. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2478. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class have an inadequate

remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 96:
Negligent Product Containers – Ohio

2479. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2480. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2481. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2482. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2483. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to

exercise reasonable care in choosing and making the containers for its products.

2484. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2485. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2486. The latent injuries from which Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2487. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2488. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2489. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

2490. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2491. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2492. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 97:
Negligent Storage and Transportation – Ohio

2493. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2494. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2495. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2496. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2497. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

2498. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2499. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and Ohio Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing

medical monitoring.

2500. The latent injuries from which Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2501. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2502. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2503. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2504. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2505. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2506. Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. West Virginia

COUNT 98:
Medical Monitoring – Negligent Failure To Warn Through Warnings And Precautions – West Virginia

2507. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2508. This cause of action is brought by Ida Adams, individually and on behalf of the

West Virginia Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2509. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2510. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Pfizer.

2511. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2512. Under West Virginia law, a manufacturer, like Defendant, has a duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

2513. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each its Ranitidine-Containing Products were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2514. Plaintiff or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2515. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of its Ranitidine-Containing Products, Plaintiff and West Virginia Pfizer OTC

Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2516. The latent injuries from which Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2517. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2518. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2519. By monitoring and testing Plaintiff, the risk that Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2520. Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2521. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2522. Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the West Virginia Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 99:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – West Virginia

2523. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2524. This cause of action is brought by Ida Adams, individually and on behalf of the West Virginia Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2525. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2526. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Pfizer.

2527. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2528. Under West Virginia law, a manufacturer, like Defendant, has a duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

2529. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2530. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2531. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of

developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2532. The latent injuries from which Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2533. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2534. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2535. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2536. Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Pfizer OTC Medical

Monitoring Class members as frequently and appropriately as necessary.

2537. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2538. Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 100:
Medical Monitoring – Negligent Product Containers – West Virginia

2539. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2540. This cause of action is brought by Ida Adams, individually and on behalf of the

West Virginia Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2541. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2542. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Pfizer.

2543. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2544. Under West Virginia law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2545. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2546. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2547. The latent injuries from which Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

2548. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2549. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2550. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2551. Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2552. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2553. Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 101:
Medical Monitoring – Negligent Storage and Transportation –West Virginia

2554. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2555. This cause of action is brought by Ida Adams, individually and on behalf of the West Virginia Pfizer OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Pfizer (for the purposes of this Count, "Defendant").

2556. The allegations in this Count apply to Pfizer during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2557. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Pfizer.

2558. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2559. Under West Virginia law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2560. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2561. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and West Virginia Pfizer OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2562. The latent injuries from which Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2563. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2564. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2565. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2566. Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2567. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Pfizer OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2568. Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Pfizer OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

D. CAUSES OF ACTION AGAINST DEFENDANT BI WITH RESPECT TO OTC ZANTAC

2569. Plaintiffs identified in the table below bring claims against Defendant BI with respect to prescription Zantac on behalf of themselves and their respective State BI OTC Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Richard Obrien	CA
Virginia Aragon	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Clifton McKinnon	FL
Gustavo Velasquez	FL
Jeannie Black	FL
Joshua Winans	FL
Marva Mccall	FL
Michael Tomlinson	FL
Ricardo Moròn	FL
Sharon Tweg	FL
Ronald Ragis	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Charles Longfield	MD

Plaintiff Name	State of Usage
Alberta Griffin	MD
Ida Adams	MD; WV
Antrenise Campbell	MO
Lorie Kendall-Songer	MO
Angel Vega	MT
Cesar Pinon	NV
Chris Troyan	OH
Michael Galloway	OH
Patricia Hess	OH
Teresa Waters	UT

1. Arizona

COUNT 102:
Negligence – Failure to Warn Through Warnings and Precautions – Arizona

2570. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2571. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

2572. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

2573. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

2574. Under Arizona law manufacturers, like Defendants, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

2575. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2576. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2577. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Arizona BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers ("Subject Cancers") and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2578. The latent injuries from which Plaintiffs and the Arizona BI OTC Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2579. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2580. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2581. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2582. Plaintiffs and the Arizona BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2583. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2584. Plaintiffs and the Arizona BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 103:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

2585. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2586. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

2587. The allegations in this Count apply to BI during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2588. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2589. Under Arizona law, manufacturers, like Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

2590. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2591. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2592. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers ("Subject Cancers") and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2593. The latent injuries from which Plaintiffs and the Arizona BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2594. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2595. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2596. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2597. Plaintiffs and the Arizona BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2598. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2599. Plaintiffs and the Arizona BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 104:
Negligent Product Containers – Arizona

2600. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2601. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

2602. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

2603. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

2604. Under Arizona law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2605. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2606. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2607. The latent injuries from which Plaintiffs and the Arizona BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2608. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2609. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2610. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2611. Plaintiffs and the Arizona BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2612. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2613. Plaintiffs and the Arizona BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 105:
Negligent Storage and Transportation –Arizona

2614. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2615. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

2616. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2617. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

2618. Under Arizona law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2619. Each Retailer and Distributor Defendant, like Defendant, breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2620. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Arizona BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers ("Subject Cancers") and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2621. The latent injuries from which Plaintiffs and the Arizona BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2622. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2623. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2624. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2625. Plaintiffs and the Arizona BI OTC Medical Monitoring Class members seek

creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2626. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2627. Plaintiffs and the Arizona BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 106:
Negligence – Failure to Warn Through Warnings and Precautions – California

2628. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2629. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, Virginia Aragon, and Jonathan Ferguson, individually and on behalf of the California BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2630. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2631. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

2632. Under California law, manufacturers, like Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

2633. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2634. Plaintiffs or their doctors would have read and heeded these warnings had they been

included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2635. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and California BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2636. The latent injuries from which Plaintiffs and the California BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2637. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2638. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2639. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

2640. Plaintiffs and the California BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2641. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2642. Plaintiffs and the California BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 107:
Negligence – Failure to Warn Through Proper Expiration Dates – California

2643. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2644. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, Virginia Aragon, and Jonathan Ferguson, individually and on behalf of the California BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2645. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2646. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2647. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

2648. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2649. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2650. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2651. The latent injuries from which Plaintiffs and the California BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2652. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2653. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2654. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2655. Plaintiffs and the California BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2656. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2657. Plaintiffs and the California BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 108:
Strict Liability –Failure to Warn Consumers Through the FDA – California

2658. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2659. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, Virginia Aragon, and Jonathan Ferguson, individually and on behalf of the California BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2660. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2661. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to BI.

2662. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

2663. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

2664. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2665. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. § 314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

2666. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

2667. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2668. The latent injuries from which Plaintiffs and the California BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

2669. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2670. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2671. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2672. Plaintiffs and the California BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2673. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2674. Plaintiffs and the California BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 109:
Negligent Product Containers –California

2675. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2676. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, Virginia Aragon, and Jonathan Ferguson, individually and on behalf of the California BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2677. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2678. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to BI.

2679. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2680. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2681. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2682. The latent injuries from which Plaintiffs and the California BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2683. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2684. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2685. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2686. Plaintiffs and the California BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2687. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2688. Plaintiffs and the California BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 110:
Negligent Storage And Transportation – California

2689. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2690. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, Virginia Aragon, and Jonathan Ferguson, individually and on behalf of the California BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2691. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2692. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

2693. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

2694. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2695. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and

transported. These high levels of NDMA caused Plaintiffs' injuries.

2696. Plaintiffs and California BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2697. The latent injuries from which Plaintiffs and the California BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2698. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2699. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2700. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2701. Plaintiffs and the California BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the California BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2702. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2703. Plaintiffs and the California BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 111:
Medical Monitoring – Negligence – Failure To Warn Through Warnings And Precautions – Colorado

2704. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2705. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2706. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2707. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

2708. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2709. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

2710. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2711. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2712. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Colorado BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2713. The latent injuries from which Plaintiffs and the Colorado BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2714. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2715. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2716. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2717. Plaintiffs and the Colorado BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2718. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2719. Plaintiffs and the Colorado BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 112:
Medical Monitoring – Negligence –Failure to Warn Through Proper Expiration Dates – Colorado

2720. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2721. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2722. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2723. Plaintiffs incorporate herein Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2724. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2725. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

2726. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2727. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2728. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Colorado BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2729. The latent injuries from which Plaintiffs and the Colorado BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2730. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2731. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2732. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2733. Plaintiffs and the Colorado BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2734. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2735. Plaintiffs and the Colorado BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 113:
Medical Monitoring – Negligent Product Containers – Colorado

2736. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2737. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2738. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2739. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

2740. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2741. Under Colorado law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2742. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2743. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Colorado BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2744. The latent injuries from which Plaintiffs and the Colorado BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2745. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2746. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2747. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2748. Plaintiffs and the Colorado BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2749. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2750. Plaintiffs and the Colorado BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 114:
Medical Monitoring – Negligent Storage and Transportation – Colorado

2751. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2752. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2753. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2754. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

2755. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2756. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2757. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2758. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Colorado BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2759. The latent injuries from which Plaintiffs and the Colorado BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2760. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2761. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2762. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2763. Plaintiffs and the Colorado BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2764. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2765. Plaintiffs and the Colorado BI OTC Medical Monitoring Class have an inadequate

remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 115:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and – PrecautionsFlorida

2766. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2767. This cause of action is brought by Clifton McKinnon, Gustavo Velasquez, Jeannie Black, Joshua Winans, Marva McCall, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Ronald Ragis, individually and on behalf of the Florida BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2768. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2769. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-

Specific Allegations) as to BI.

2770. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2771. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

2772. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2773. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2774. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2775. The latent injuries from which Plaintiffs and the Florida BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2776. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2777. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2778. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2779. Plaintiffs and the Florida BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2780. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2781. Plaintiffs and the Florida BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 116:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Florida

2782. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2783. This cause of action is brought by Clifton McKinnon, Gustavo Velasquez, Jeannie Black, Joshua Winans, Marva McCall, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Ronald Ragis, individually and on behalf of the Florida BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2784. The allegations in this Count apply to BI during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2785. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2786. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2787. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

2788. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2789. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2790. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2791. The latent injuries from which Plaintiffs and the Florida BI OTC Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2792. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2793. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2794. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2795. Plaintiffs and the Florida BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2796. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2797. Plaintiffs and the Florida BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 117:
Medical Monitoring – Negligent Product Contain – Florida

2798. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2799. This cause of action is brought by Clifton McKinnon, Gustavo Velasquez, Jeannie Black, Joshua Winans, Marva McCall, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Ronald Ragis, individually and on behalf of the Florida BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2800. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2801. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

2802. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

2803. Under Florida law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2804. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2805. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2806. The latent injuries from which Plaintiffs and the Florida BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2807. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2808. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2809. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2810. Plaintiffs and the Florida BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2811. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2812. Plaintiffs and the Florida BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term

physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 118:
Medical Monitoring – Negligent Storage and Transportation – Florida

2813. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7–24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2814. This cause of action is brought by Clifton McKinnon, Gustavo Velasquez, Jeannie Black, Joshua Winans, Marva McCall, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Ronald Ragis, individually and on behalf of the Florida BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2815. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2816. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

2817. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

2818. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2819. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2820. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Florida BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2821. The latent injuries from which Plaintiffs and the Florida BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2822. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2823. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

2824. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2825. Plaintiffs and the Florida BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2826. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2827. Plaintiffs and the Florida BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 119:
Negligence – Failure to Warn Through Warnings And Precautions – Indiana

2828. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2829. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2830. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2831. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

2832. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

2833. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after

manufacture.

2834. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2835. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Indiana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2836. The latent injuries from which Plaintiffs and the Indiana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2837. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2838. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2839. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2840. Plaintiffs and the Indiana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2841. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2842. Plaintiffs and the Indiana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 120: Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

2843. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2844. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2845. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2846. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2847. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

2848. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2849. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2850. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2851. The latent injuries from which Plaintiffs and the Indiana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2852. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2853. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2854. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2855. Plaintiffs and the Indiana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2856. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2857. Plaintiffs and the Indiana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 121:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

2858. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing

Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2859. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2860. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2861. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to BI.

2862. Under Indiana law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

2863. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

2864. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2865. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. § 314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

2866. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

2867. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2868. The latent injuries from which Plaintiffs and the Indiana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2869. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2870. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2871. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2872. Plaintiffs and the Indiana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2873. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2874. Plaintiffs and the Indiana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-

approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 122:
Negligent Product Containers – Indiana

2875. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2876. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

2877. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2878. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

2879. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2880. Defendant breached this duty by failing to utilize containers that would minimize

the NDMA produced in its Ranitidine-Containing Products.

2881. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2882. The latent injuries from which Plaintiffs and the Indiana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2883. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2884. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2885. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2886. Plaintiffs and the Indiana BI OTC Medical Monitoring Class members seek

creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2887. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2888. Plaintiffs and the Indiana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 123:
Negligent Storage and Transportation – Indiana

2889. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2890. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

2891. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2892. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

2893. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

2894. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2895. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiff' injuries.

2896. Plaintiffs and Indiana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2897. The latent injuries from which Plaintiffs and the Indiana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2898. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2899. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2900. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2901. Plaintiffs and the Indiana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2902. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2903. Plaintiffs and the Indiana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 124:
Negligence –Failure to Warn Through Warnings and Precautions – Maryland

2904. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2905. This cause of action is brought by Charles Longfield, Alberta Griffin, and Ida Adams, individually and on behalf of the Maryland BI OTC Medical Monitoring Class (for the

purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2906. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2907. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

2908. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

2909. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2910. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2911. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Maryland BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2912. The latent injuries from which Plaintiffs and the Maryland BI OTC Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2913. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2914. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2915. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2916. Plaintiffs and the Maryland BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2917. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2918. Plaintiffs and the Maryland BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 125:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

2919. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2920. This cause of action is brought by Charles Longfield, Alberta Griffin, and Ida Adams, individually and on behalf of the Maryland BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2921. The allegations in this Count apply to BI during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2922. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2923. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

2924. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

2925. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2926. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2927. The latent injuries from which Plaintiffs and the Maryland BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

2928. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2929. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2930. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2931. Plaintiffs and the Maryland BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2932. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2933. Plaintiffs and the Maryland BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 126:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

2934. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2935. This cause of action is brought by Charles Longfield, Alberta Griffin, and Ida Adams, individually and on behalf of the Maryland BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2936. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2937. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to BI.

2938. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

2939. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

2940. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

2941. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendants failed to warn anyone through any medium.

2942. Specifically, Defendants failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks

that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

2943. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2944. The latent injuries from which Plaintiffs and the Maryland BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2945. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2946. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2947. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland BI

OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2948. Plaintiffs and the Maryland BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2949. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2950. Plaintiffs and the Maryland BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 127:
Negligent Product Containers– Maryland

2951. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2952. This cause of action is brought by Charles Longfield, Alberta Griffin, and Ida Adams, individually and on behalf of the Maryland BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2953. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2954. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

2955. Under Maryland law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

2956. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

2957. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2958. The latent injuries from which Plaintiffs and the Maryland BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2959. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2960. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2961. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2962. Plaintiffs and the Maryland BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2963. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2964. Plaintiffs and the Maryland BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 128:
Negligent Storage and Transportation – Maryland

2965. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2966. This cause of action is brought by Charles Longfield, Alberta Griffin, and Ida Adams, individually and on behalf of the Maryland BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2967. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2968. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

2969. Under Maryland law, Defendant has a duty to exercise reasonable care in transporting and storing products.

2970. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

2971. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Maryland BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2972. The latent injuries from which Plaintiffs and the Maryland BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2973. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

2974. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2975. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2976. Plaintiffs and the Maryland BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2977. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2978. Plaintiffs and the Maryland BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-

approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 129:
Negligence – Failure to Warn Through Warnings and Precautions –Missouri

2979. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2980. This cause of action is brought by Antrenise Campbell and Lorie Kendall-Songer, individually and on behalf of the Missouri BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2981. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2982. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

2983. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

2984. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

2985. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

2986. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Missouri BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

2987. The latent injuries from which Plaintiffs and the Missouri BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

2988. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

2989. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

2990. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

2991. Plaintiffs and the Missouri BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

2992. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

2993. Plaintiffs and the Missouri BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs

and the Missouri BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 130:
Negligence –Failure to Warn Through Proper Expiration Dates – Missouri

2994. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

2995. This cause of action is brought by Antrenise Campbell and Lorie Kendall-Songer, individually and on behalf of the Missouri BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

2996. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

2997. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

2998. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

2999. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3000. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3001. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3002. The latent injuries from which Plaintiffs and the Missouri BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3003. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3004. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3005. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3006. Plaintiffs and the Missouri BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3007. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3008. Plaintiffs and the Missouri BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 131:
Strict Liability – Failure to Warn Consumers Through the FDA – Missouri

3009. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3010. This cause of action is brought by Antrenise Campbell and Lorie Kendall-Songer, individually and on behalf of the Missouri BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3011. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3012. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to BI.

3013. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

3014. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor,

manufacturers, such as Defendant, have a state law duty to do so.

3015. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

3016. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

3017. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

3018. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3019. The latent injuries from which Plaintiffs and the Missouri BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3020. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3021. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3022. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3023. Plaintiffs and the Missouri BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3024. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Missouri BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3025. Plaintiffs and the Missouri BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 132:
Negligent Product Containers – Missouri

3026. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3027. This cause of action is brought by Antrenise Campbell and Lorie Kendall-Songer, individually and on behalf of the Missouri BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3028. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3029. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

3030. Under Missouri law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3031. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3032. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

3033. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3034. The latent injuries from which Plaintiffs and the Missouri BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3035. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

3036. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3037. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3038. Plaintiffs and the Missouri BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3039. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3040. Plaintiffs and the Missouri BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs

and the Missouri BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 133:
Negligent Storage and Transportation – Missouri

3041. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3042. This cause of action is brought by Antrenise Campbell and Lorie Kendall-Songer, individually and on behalf of the Missouri BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3043. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3044. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

3045. Under Missouri law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3046. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

3047. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold. These high levels of NDMA caused Plaintiffs' injuries.

3048. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiff' injuries.

3049. Plaintiffs and Missouri BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3050. The latent injuries from which Plaintiffs and the Missouri BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3051. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3052. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

3053. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3054. Plaintiffs and the Missouri BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3055. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3056. Plaintiffs and the Missouri BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Montana

COUNT 134:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Montana

3057. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3058. This cause of action is brought by Angel Vega, individually and on behalf of the Montana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3059. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3060. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

3061. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3062. Under Montana law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3063. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk

of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3064. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3065. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Montana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3066. The latent injuries from which Plaintiffs and the Montana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3067. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3068. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3069. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Montana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3070. Plaintiffs and the Montana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Montana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Montana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3071. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Montana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3072. Plaintiffs and the Montana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Montana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 135:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Montana

3073. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3074. This cause of action is brought by Angel Vega, individually and on behalf of the Montana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3075. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3076. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

3077. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3078. Under Montana law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3079. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3080. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3081. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Montana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3082. The latent injuries from which Plaintiffs and the Montana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3083. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3084. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3085. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Montana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3086. Plaintiffs and the Montana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Montana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Montana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3087. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Montana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3088. Plaintiffs and the Montana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Montana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 136:
Medical Monitoring – Negligent Product Containers – Montana

3089. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3090. This cause of action is brought by Angel Vega, individually and on behalf of the Montana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3091. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3092. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

3093. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3094. Under Montana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3095. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3096. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused

Plaintiffs' injuries.

3097. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Montana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3098. The latent injuries from which Plaintiffs and the Montana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3099. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3100. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3101. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Montana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3102. Plaintiffs and the Montana BI OTC Medical Monitoring Class members seek

creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Montana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Montana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3103. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Montana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3104. Plaintiffs and the Montana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Montana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 137:
Medical Monitoring – Negligent Storage and Transportation – Montana

3105. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3106. This cause of action is brought by Angel Vega, individually and on behalf of the Montana BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3107. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3108. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

3109. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3110. Under Montana law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3111. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3112. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold. These high levels of NDMA caused Plaintiffs' injuries.

3113. Plaintiffs and Montana BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

3114. The latent injuries from which Plaintiffs and the Montana BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3115. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3116. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3117. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Montana BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3118. Plaintiffs and the Montana BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Montana BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Montana BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3119. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Montana BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3120. Plaintiffs and the Montana BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Montana BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Nevada

COUNT 138:
Negligence – Failure to Warn Through Warnings and Precautions – Nevada

3121. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3122. This cause of action is brought by Cesar Pinon, individually and on behalf of the

Nevada BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3123. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3124. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

3125. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3126. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3127. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3128. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Nevada BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3129. The latent injuries from which Plaintiffs and the Nevada BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3130. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3131. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3132. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3133. Plaintiffs and the Nevada BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3134. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3135. Plaintiffs and the Nevada BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 139:
Negligence –Failure to Warn Through Proper Expiration Dates – Nevada

3136. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3137. This cause of action is brought by Cesar Pinon, individually and on behalf of the Nevada BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3138. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3139. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

3140. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3141. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3142. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3143. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Nevada BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3144. The latent injuries from which Plaintiffs and the Nevada BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3145. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3146. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3147. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3148. Plaintiffs and the Nevada BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3149. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada BI OTC Medical Monitoring Class members in writing that they may require

frequent medical monitoring for the purpose of diagnosis.

3150. Plaintiffs and the Nevada BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 140:
Negligence – Failure to Warn Consumers Through the FDA – Nevada

3151. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3152. This cause of action is brought by Cesar Pinon, individually and on behalf of the Nevada BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3153. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3154. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-

Specific Allegations) as to BI.

3155. "Nevada law contains a parallel requirement [to federal law] because it imposes a continuing duty on manufacturers to warn of defects in their products." *Scovil v. Medtronic Inc.*, No. 2:14-CV-00213-APG, 2015 WL 880614, at *7 (D. Nev. Mar. 2, 2015); *see also Forest v. E.I. DuPont de Nemours & Co.*, 791 F. Supp. 1460, 1464 (D. Nev. 1992) (discussing Restatement (Second) § 388 and explaining that at the summary judgment stage, "negligence and strict liability claims should be considered together" and that on failure to warn the "Nevada formulation is based on California common law").

3156. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

3157. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

3158. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

3159. Specifically, Defendants failed to submit adverse event reports related to cancer for

ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

3160. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Nevada BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3161. The latent injuries from which Plaintiffs and the Nevada BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3162. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3163. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3164. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada BI OTC

Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3165. Plaintiffs and the Nevada BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3166. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3167. Plaintiffs and the Nevada BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 141:
Negligent Product Containers – Nevada

3168. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3169. This cause of action is brought by Cesar Pinon, individually and on behalf of the Nevada BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3170. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3171. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

3172. Under Nevada law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3173. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3174. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products each Manufacturer Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

3175. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Nevada BI OTC

Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3176. The latent injuries from which Plaintiffs and the Nevada BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3177. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3178. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3179. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3180. Plaintiffs and the Nevada BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical

monitoring and diagnosis of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3181. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3182. Plaintiffs and the Nevada BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 142:
Negligent Storage and Transportation – Nevada

3183. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3184. This cause of action is brought by Cesar Pinon, individually and on behalf of the Nevada BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3185. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3186. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

3187. Under Nevada law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3188. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3189. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold. These high levels of NDMA caused Plaintiffs' injuries.

3190. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and Nevada BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3191. The latent injuries from which Plaintiffs and the Nevada BI OTC Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3192. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3193. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3194. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3195. Plaintiffs and the Nevada BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3196. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3197. Plaintiffs and the Nevada BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. Ohio

COUNT 143:
Strict Liability – Failure to Warn Through Warnings and Precautions – Ohio

3198. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3199. This cause of action is brought by Chris Troyan, Michael Galloway, and Patricia Hess, individually and on behalf of the Ohio BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3200. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3201. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

3202. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

3203. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3204. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3205. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Ohio BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3206. The latent injuries from which Plaintiffs and the Ohio BI OTC Medical Monitoring

Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3207. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3208. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3209. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3210. Plaintiffs and the Ohio BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3211. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3212. Plaintiffs and the Ohio BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 144:
Strict Liability – Failure to Warn Through Proper Expiration Dates – Ohio

3213. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3214. This cause of action is brought by Chris Troyan, Michael Galloway, and Patricia Hess, individually and on behalf of the Ohio BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3215. The allegations in this Count apply to BI during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3216. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

3217. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

3218. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3219. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3220. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3221. The latent injuries from which Plaintiffs and the Ohio BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed

to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3222. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3223. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3224. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3225. Plaintiffs and the Ohio BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3226. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3227. Plaintiffs and the Ohio BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 145:
Negligent Product Containers – Ohio

3228. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3229. This cause of action is brought by Chris Troyan, Michael Galloway, and Patricia Hess, individually and on behalf of the Ohio BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3230. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3231. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

3232. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3233. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3234. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

3235. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3236. The latent injuries from which Plaintiffs and the Ohio BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3237. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

3238. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3239. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3240. Plaintiffs and the Ohio BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3241. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3242. Plaintiffs and the Ohio BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs

and the Ohio BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 146:
Negligent Storage And Transportation – Ohio

3243. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3244. This cause of action is brought by Chris Troyan, Michael Galloway, and Patricia Hess, individually and on behalf of the Ohio BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3245. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3246. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

3247. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

3248. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

3249. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and Ohio BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3250. The latent injuries from which Plaintiffs and the Ohio BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3251. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3252. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3253. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3254. Plaintiffs and the Ohio BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3255. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3256. Plaintiffs and the Ohio BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. Utah

COUNT 147:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Utah

3257. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3258. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3259. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3260. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

3261. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3262. Under Utah law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3263. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3264. Plaintiffs or their doctors would have read and heeded these warnings had they been

included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3265. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Utah BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3266. The latent injuries from which Plaintiffs and the Utah BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3267. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3268. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3269. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without

adequate treatment will be significantly reduced.

3270. Plaintiffs and the Utah BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3271. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3272. Plaintiffs and the Utah BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 148:
Medical Monitoring – Negligence – Failure To Warn Through Proper Expiration Dates – Utah

3273. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3274. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3275. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3276. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

3277. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3278. Under Utah law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3279. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3280. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

3281. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Utah BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3282. The latent injuries from which Plaintiffs and the Utah BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3283. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3284. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3285. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3286. Plaintiffs and the Utah BI OTC Medical Monitoring Class members seek creation

of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3287. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3288. Plaintiffs and the Utah BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 149:
Medical Monitoring – Negligent Product Containers –Utah

3289. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3290. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3291. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3292. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

3293. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3294. Under Utah law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3295. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3296. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

3297. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing

Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3298. The latent injuries from which Plaintiffs and the Utah BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3299. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3300. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3301. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3302. Plaintiffs and the Utah BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah BI OTC Medical Monitoring Class members as frequently

and appropriately as necessary.

3303. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3304. Plaintiffs and the Utah BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 150:
Medical Monitoring – Negligent Storage and Transportation – Utah

3305. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3306. This cause of action is brought by Teresa Waters, individually and on behalf of the

Utah BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs") , against BI (for the purposes of this Count, "Defendant").

3307. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3308. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

3309. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3310. Under Utah law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3311. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3312. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Utah BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3313. The latent injuries from which Plaintiffs and the Utah BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting

Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3314. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3315. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3316. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3317. Plaintiffs and the Utah BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3318. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah BI OTC Medical Monitoring Class members in writing that they may require

frequent medical monitoring for the purpose of diagnosis.

3319. Plaintiffs and the Utah BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

12. West Virginia

COUNT 151:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – West Virginia

3320. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3321. This cause of action is brought by Ida Adams, individually and on behalf of the West Virginia BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3322. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3323. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to BI.

3324. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3325. Under West Virginia law, a manufacturer, like Defendant, has a duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

3326. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each its Ranitidine-Containing Products were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3327. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3328. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of its Ranitidine-Containing Products, Plaintiff and West Virginia BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3329. The latent injuries from which Plaintiff and the West Virginia BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3330. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3331. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3332. By monitoring and testing Plaintiff, the risk that Plaintiff and the West Virginia BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3333. Plaintiff and the West Virginia BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the West Virginia BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the West Virginia BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3334. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3335. Plaintiff and the West Virginia BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the West Virginia BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 152:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – West Virginia

3336. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3337. This cause of action is brought by Ida Adams, individually and on behalf of the West Virginia BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3338. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

3339. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to BI.

3340. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3341. Under West Virginia law, a manufacturer, like Defendant, has a duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

3342. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3343. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3344. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3345. The latent injuries from which Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3346. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3347. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3348. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3349. Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3350. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all West Virginia BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3351. Plaintiffs and the West Virginia BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 153:
Medical Monitoring – Negligent Product Containers – West Virginia

3352. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3353. This cause of action is brought by Ida Adams, individually and on behalf of the West Virginia BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3354. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3355. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to BI.

3356. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3357. Under West Virginia law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3358. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3359. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3360. The latent injuries from which Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3361. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3362. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3363. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3364. Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3365. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3366. Plaintiffs and the West Virginia BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members will continue to face

an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 154:
Medical Monitoring – Negligent Storage and Transportation –West Virginia

3367. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3368. This cause of action is brought by Ida Adams, individually and on behalf of the West Virginia BI OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against BI (for the purposes of this Count, "Defendant").

3369. The allegations in this Count apply to BI during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3370. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to BI.

3371. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3372. Under West Virginia law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3373. Defendant breached this duty by failing to implement or enforce policies to ensure

Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3374. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and West Virginia BI OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3375. The latent injuries from which Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3376. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3377. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3378. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3379. Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3380. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia BI OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3381. Plaintiffs and the West Virginia BI OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia BI OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

E. CAUSES OF ACTION AGAINST DEFENDANT SANOFI WITH RESPECT TO OTC ZANTAC

3382. Plaintiffs identified in the table below bring claims against Defendant Sanofi with respect to prescription Zantac on behalf of themselves and their respective State Sanofi OTC Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff

incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Richard Obrien	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Gustavo Velasquez	FL
Jeannie Black	FL
Joshua Winans	FL
Michael Tomlinson	FL
Ricardo Moròn	FL
Sharon Tweg	FL
Sonia Diaz	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Alberta Griffin	MD
Ida Adams	MD
Lorie Kendall-Songer	MO
Chris Troyan	OH
Michael Galloway	OH
Teresa Waters	UT

1. Arizona

COUNT 155:
Negligence – Failure to Warn Through Warnings and Precautions – Arizona

3383. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3384. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3385. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3386. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3387. Under Arizona law manufacturers, like Defendants, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

3388. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after

manufacture.

3389. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3390. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Arizona Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3391. The latent injuries from which Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3392. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3393. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3394. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3395. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3396. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3397. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 156:
Negligence –Failure to Warn Through Proper Expiration Dates – Arizona

3398. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3399. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3400. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3401. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3402. Under Arizona law, manufacturers, like Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

3403. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3404. Plaintiffs or their doctors would have read and heeded these warnings had they been

included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3405. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3406. The latent injuries from which Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3407. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3408. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3409. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

3410. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3411. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3412. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 157: Negligent Product Containers – Arizona

3413. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3414. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3415. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3416. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3417. Under Arizona law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3418. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3419. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3420. The latent injuries from which Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3421. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3422. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3423. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3424. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3425. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3426. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 158:
Negligent Storage and Transportation –Arizona

3427. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3428. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3429. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

3430. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3431. Under Arizona law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3432. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3433. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold. These high levels of NDMA caused Plaintiffs' injuries.

3434. Plaintiffs and Arizona Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3435. The latent injuries from which Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3436. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3437. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3438. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3439. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3440. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3441. Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 159:
Negligence –Failure to Warn Through Warnings and Precautions –California

3442. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3443. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3444. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3445. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3446. Under California law, manufacturers, like Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized

and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

3447. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3448. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3449. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and California Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3450. The latent injuries from which Plaintiffs and the California Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3451. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3452. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3453. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3454. Plaintiffs and the California Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3455. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3456. Plaintiffs and the California Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 160:
Negligence – Failure to Warn Through Proper Expiration Dates – California

3457. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3458. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3459. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3460. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3461. Under California law, manufacturers, including Defendant, have a duty of

reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

3462. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3463. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3464. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3465. The latent injuries from which Plaintiffs and the California Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3466. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3467. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3468. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3469. Plaintiffs and the California Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3470. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3471. Plaintiffs and the California Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 161:
Strict Liability –Failure to Warn Consumers Through the FDA –California

3472. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3473. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3474. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3475. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Sanofi.

3476. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes

"a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

3477. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

3478. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

3479. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. § 314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

3480. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

3481. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Sanofi OTC

Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3482. The latent injuries from which Plaintiffs and the California Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3483. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3484. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3485. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3486. Plaintiffs and the California Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3487. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3488. Plaintiffs and the California Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 162:
Negligent Product Containers – California

3489. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine

and injury), as if fully stated herein.

3490. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3491. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3492. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3493. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3494. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3495. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3496. The latent injuries from which Plaintiffs and the California Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3497. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3498. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3499. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3500. Plaintiffs and the California Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3501. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sanofi OTC Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

3502. Plaintiffs and the California Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 163:
Negligent Storage And Transportation – California

3503. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3504. This cause of action is brought by Golbenaz Bakhtiar, Richard Obrien, and Virginia Aragon, individually and on behalf of the California Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3505. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3506. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3507. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

3508. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3509. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

3510. Plaintiffs and California Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3511. The latent injuries from which Plaintiffs and the California Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3512. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

3513. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3514. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3515. Plaintiffs and the California Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3516. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3517. Plaintiffs and the California Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 164:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Colorado

3518. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3519. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3520. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3521. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3522. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3523. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care

to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

3524. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3525. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3526. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Colorado Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3527. The latent injuries from which Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3528. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3529. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3530. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3531. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3532. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3533. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 165:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Colorado

3534. Plaintiffs incorporate by reference each allegation set forth in -24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3535. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3536. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3537. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3538. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3539. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

3540. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3541. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3542. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Colorado Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3543. The latent injuries from which Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3544. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3545. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3546. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3547. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3548. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3549. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 166:
Medical Monitoring – Negligent Product Containers – Colorado

3550. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3551. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3552. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3553. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3554. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3555. Under Colorado law, a pharmaceutical manufacturer, like Defendant, has a duty to

exercise reasonable care in choosing and making the containers for its products.

3556. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3557. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Colorado Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3558. The latent injuries from which Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3559. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3560. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3561. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

3562. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3563. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3564. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 167:
Medical Monitoring – Negligent Storage and Transportation – Colorado

3565. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3566. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3567. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3568. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3569. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3570. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3571. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3572. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold. These high levels of NDMA caused Plaintiffs' injuries.

3573. Plaintiffs and Colorado Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3574. The latent injuries from which Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3575. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3576. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3577. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3578. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3579. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3580. Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 168:
Medical Monitoring –Negligence –Failure to Warn Through Warnings and Precautions – Florida

3581. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine

and injury), as if fully stated herein.

3582. This cause of action is brought by Gustavo Velasquez, Jeannie Black, Joshua Winans, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Sonia Diaz, individually and on behalf of the Florida Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3583. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3584. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3585. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3586. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

3587. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3588. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3589. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3590. The latent injuries from which Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3591. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3592. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3593. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3594. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3595. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3596. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 169:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Florida

3597. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-

91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3598. This cause of action is brought by Gustavo Velasquez, Jeannie Black, Joshua Winans, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Sonia Diaz, individually and on behalf of the Florida Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3599. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3600. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3601. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3602. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

3603. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3604. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3605. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3606. The latent injuries from which Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3607. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3608. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3609. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sanofi

OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3610. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3611. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3612. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 170:
Medical Monitoring – Negligent Product Containers – Florida

3613. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24

(describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3614. This cause of action is brought by Gustavo Velasquez, Jeannie Black, Joshua Winans, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Sonia Diaz, individually and on behalf of the Florida Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3615. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3616. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3617. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3618. Under Florida law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3619. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3620. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused

Plaintiffs' injuries.

3621. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3622. The latent injuries from which Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3623. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3624. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3625. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3626. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members seek

creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3627. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3628. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 171:
Medical Monitoring – Negligent Storage and Transportation – Florida

3629. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3630. This cause of action is brought by Gustavo Velasquez, Jeannie Black, Joshua Winans, Michael Tomlinson, Ricardo Moron, Sharon Tweg, and Sonia Diaz, individually and on behalf of the Florida Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3631. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3632. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3633. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3634. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3635. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3636. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold. These high levels of NDMA caused Plaintiffs' injuries.

3637. Plaintiffs and Florida Sanofi OTC Medical Monitoring Class members have

sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3638. The latent injuries from which Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3639. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3640. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3641. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3642. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sanofi OTC Medical Monitoring

Class members as frequently and appropriately as necessary.

3643. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3644. Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 172:
Negligence – Failure to Warn Through Warnings and Precautions – Indiana

3645. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3646. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3647. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3648. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3649. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

3650. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3651. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3652. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Indiana Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses

associated with ongoing medical monitoring.

3653. The latent injuries from which Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3654. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3655. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3656. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3657. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3658. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3659. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 173:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

3660. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3661. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana Sanofi OTC Medical Monitoring Class (for the

purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3662. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3663. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3664. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

3665. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3666. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3667. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3668. The latent injuries from which Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3669. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3670. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3671. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3672. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3673. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3674. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 174:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

3675. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3676. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3677. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3678. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Sanofi.

3679. Under Indiana law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

3680. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

3681. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

3682. Under federal regulations, Brand Manufacturer Defendants, including Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. *See* 21 C.F.R. § 314.70. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, including Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendant failed to warn anyone through any medium.

3683. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks

that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

3684. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3685. The latent injuries from which Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3686. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3687. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3688. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3689. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3690. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3691. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 175:
Negligent Product Containers – Indiana

3692. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3693. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3694. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3695. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3696. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3697. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3698. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3699. The latent injuries from which Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3700. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3701. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3702. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3703. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3704. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3705. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 176:
Negligent Storage and Transportation – Indiana

3706. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3707. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Tracy Wells, individually and on behalf of the Indiana Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3708. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

3709. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3710. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

3711. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3712. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and Indiana Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3713. The latent injuries from which Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3714. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

3715. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3716. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3717. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3718. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3719. Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Indiana Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 177:
Negligence – Failure to Warn Through Warnings and Precautions – Maryland

3720. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3721. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3722. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3723. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3724. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

3725. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3726. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3727. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Maryland Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3728. The latent injuries from which Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3729. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

3730. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3731. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3732. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3733. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3734. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 178:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

3735. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3736. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3737. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3738. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3739. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

3740. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3741. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3742. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3743. The latent injuries from which Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3744. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3745. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3746. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3747. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3748. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3749. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 179:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

3750. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3751. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3752. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3753. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Sanofi.

3754. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

3755. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the

FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers, like Defendant, may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

3756. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

3757. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Defendants failed to warn anyone through any medium.

3758. Specifically, Defendants failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

3759. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses

and expenses associated with ongoing medical monitoring.

3760. The latent injuries from which Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3761. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3762. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3763. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3764. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3765. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3766. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 180:
Negligent Product Containers – Maryland

3767. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3768. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Sanofi OTC Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3769. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3770. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3771. Under Maryland law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3772. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3773. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

3774. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3775. The latent injuries from which Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

3776. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3777. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3778. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3779. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3780. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3781. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 181:
Negligent Storage and Transportation – Maryland

3782. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3783. This cause of action is brought by Alberta Griffin and Ida Adams, individually and on behalf of the Maryland Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3784. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3785. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3786. Under Maryland law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3787. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3788. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiffs and Maryland Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3789. The latent injuries from which Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3790. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3791. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

3792. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3793. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3794. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3795. Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 182:
Negligence – Failure to Warn Through Warnings and Precautions – Missouri

3796. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3797. This cause of action is brought by Lorie Kendall-Songer, individually and on behalf of the Missouri Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3798. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3799. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3800. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3801. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after

manufacture.

3802. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3803. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Missouri Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3804. The latent injuries from which Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3805. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3806. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3807. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3808. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3809. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3810. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 183:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

3811. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3812. This cause of action is brought by Lorie Kendall-Songer, individually and on behalf of the Missouri Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3813. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3814. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3815. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3816. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3817. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

3818. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3819. The latent injuries from which Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3820. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3821. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3822. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3823. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members seek

creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3824. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3825. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 184:
Strict Liability – Failure to Warn Consumers Through the FDA – Missouri

3826. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3827. This cause of action is brought by Lorie Kendall-Songer, individually and on behalf of the Missouri Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3828. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3829. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Sanofi.

3830. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

3831. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers, such as Defendant, have a state law duty to do so.

3832. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

3833. Under federal regulations, Brand Manufacturer Defendants, like Defendant, are able to revise the warnings on their branded products when new information arises or new analyses are performed. As an alternative theory of breach, if this method of warning consumers was unavailable, slower, or less effective, Brand Manufacturer Defendants, like Defendant, had a duty to warn the FDA as a third party who would disseminate information to the public. Brand Manufacturer Defendants failed to warn anyone through any medium.

3834. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

3835. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3836. The latent injuries from which Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3837. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3838. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3839. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3840. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3841. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3842. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 185:
Negligent Product Containers – Missouri

3843. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3844. This cause of action is brought by Lorie Kendall-Songer, individually and on behalf of the Missouri Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3845. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3846. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3847. Under Missouri law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3848. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3849. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3850. The latent injuries from which Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3851. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3852. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3853. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3854. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3855. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3856. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 186:
Negligent Storage and Transportation – Missouri

3857. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of

ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3858. This cause of action is brought by Lorie Kendall-Songer, individually and on behalf of the Missouri Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3859. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3860. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3861. Under Missouri law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3862. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3863. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and Missouri Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3864. The latent injuries from which Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3865. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3866. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3867. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3868. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3869. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3870. Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Ohio

COUNT 187:
Strict Liability – Failure to Warn Through Warnings and Precautions – Ohio

3871. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3872. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Sanofi OTC Medical Monitoring Class (for the purposes of

this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3873. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3874. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3875. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

3876. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3877. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3878. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Ohio Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3879. The latent injuries from which Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3880. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3881. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3882. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3883. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3884. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3885. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 188:
Strict Liability – Failure to Warn Through Proper Expiration Dates – Ohio

3886. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3887. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3888. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3889. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Sanofi.

3890. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

3891. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3892. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3893. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3894. The latent injuries from which Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3895. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3896. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3897. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3898. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3899. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3900. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 189:
Negligent Product Containers – Ohio

3901. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3902. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3903. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs

152-71, which are incorporated by reference.

3904. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3905. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3906. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3907. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

3908. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3909. The latent injuries from which Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3910. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3911. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3912. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3913. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3914. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3915. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-

approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 190:
Negligent Storage and Transportation – Ohio

3916. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3917. This cause of action is brought by Chris Troyan and Michael Galloway, individually and on behalf of the Ohio Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3918. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3919. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3920. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

3921. Defendant breached this duty by failing to implement or enforce policies to ensure

Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3922. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiffs' injuries.

3923. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported. These high levels of NDMA caused Plaintiff' injuries.

3924. Plaintiff and Ohio Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3925. The latent injuries from which Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3926. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3927. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3928. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3929. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3930. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3931. Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Utah

COUNT 191:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Utah

3932. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3933. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3934. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3935. Plaintiffs incorporate herein by reference Paragraphs 841-79 (Additional Count-Specific Allegations) as to Sanofi.

3936. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3937. Under Utah law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3938. Defendant breached this duty for its Ranitidine-Containing Products. The warnings

included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

3939. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3940. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Utah Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3941. The latent injuries from which Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3942. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3943. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3944. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3945. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3946. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3947. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will continue to face an

unreasonable risk of injury and disability and remain undiagnosed.

COUNT 192:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Utah

3948. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3949. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3950. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3951. Plaintiffs incorporate herein by reference as to Sanofi.

3952. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3953. Under Utah law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

3954. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

3955. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

3956. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Utah Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3957. The latent injuries from which Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3958. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3959. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3960. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3961. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3962. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3963. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 193:
Medical Monitoring – Negligent Product Containers – Utah

3964. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3965. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3966. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3967. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Sanofi.

3968. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3969. Under Utah law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

3970. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

3971. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused

Plaintiffs' injuries.

3972. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3973. The latent injuries from which Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3974. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3975. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3976. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3977. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members seek

creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3978. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3979. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 194:
Medical Monitoring – Negligent Storage and Transportation – Utah

3980. Plaintiffs incorporate by reference each allegation set forth in paragraphs 7-24 (describing Brand Manufacturer Defendants), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing

failure to notify FDA), 332-59 (describing good manufacturing practices), 384-427 (describing Brand OTC Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3981. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sanofi OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sanofi (for the purposes of this Count, "Defendant").

3982. The allegations in this Count apply to Sanofi during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 152-71, which are incorporated by reference.

3983. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Sanofi.

3984. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

3985. Under Utah law, Defendant has a duty to exercise reasonable care in transporting and storing products.

3986. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

3987. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant handled and sold, and therefore Plaintiff and Utah Sanofi OTC Medical Monitoring Class members have sustained a significantly increased risk of developing Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3988. The latent injuries from which Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3989. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

3990. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

3991. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3992. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members as frequently and appropriately as necessary.

3993. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sanofi OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3994. Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sanofi OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

F. CAUSES OF ACTION AGAINST DEFENDANT AMNEAL WITH RESPECT TO PRESCRIPTION RANITIDINE

3995. Plaintiffs identified in the table below bring claims against Defendant Amneal with respect to prescription ranitidine on behalf of themselves and their respective State Amneal Prescription Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Kevin Nelson	DC

Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Joyce Taylor	FL
Alexander Monger	FL
Laura Monger	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH; FL
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

1. Arizona

COUNT 195:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

3996. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

3997. This cause of action is brought by Armando Tapia individually and on behalf of the Arizona Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

3998. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

3999. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4000. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

4001. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4002. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4003. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancerssustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4004. The latent injuries from which Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4005. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4006. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4007. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4008. Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4009. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4010. Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 196:
Negligent Product Containers – Arizona

4011. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4012. This cause of action is brought by Armando Tapia individually and on behalf of the Arizona Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4013. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4014. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4015. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4016. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4017. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Amneal Prescription Medical Monitoring Class members have sustained a significantly increased

risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4018. The latent injuries from which Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4019. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4020. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4021. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4022. Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Amneal Prescription

Medical Monitoring Class members as frequently and appropriately as necessary.

4023. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4024. Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 197:
Negligent Storage and Transportation – Arizona

4025. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4026. This cause of action is brought by Armando Tapia individually and on behalf of the Arizona Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4027. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4028. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4029. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4030. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4031. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Arizona Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4032. The latent injuries from which Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4033. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4034. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4035. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4036. Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4037. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Amneal Prescription Medical Monitoring Class members in writing that they

may require frequent medical monitoring for the purpose of diagnosis.

4038. Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 198:
Negligence – Failure to Warn Through Proper Expiration Dates – California

4039. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4040. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon individually and on behalf of the California Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4041. The allegations in this Count apply to Amneal during the time period in which it

was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4042. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4043. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

4044. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4045. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4046. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4047. The latent injuries from which Plaintiffs and the California Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4048. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4049. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4050. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4051. Plaintiffs and the California Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4052. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Amneal Prescription Medical Monitoring Class members in writing that

they may require frequent medical monitoring for the purpose of diagnosis.

4053. Plaintiffs and the California Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 199:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

4054. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4055. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon individually and on behalf of the California Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4056. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

4057. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4058. Under California law, manufacturers (including Defendant) bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

4059. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4060. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4061. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

4062. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that

were available, including ordinary correspondence with the agency or regulatory reporting.

4063. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4064. The latent injuries from which Plaintiffs and the California Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4065. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4066. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4067. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4068. Plaintiffs and the California Amneal Prescription Medical Monitoring Class

members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4069. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4070. Plaintiffs and the California Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 200:
Negligent Product Containers – California

4071. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4072. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon individually and on behalf of the California Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4073. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4074. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4075. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4076. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4077. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4078. The latent injuries from which Plaintiffs and the California Amneal Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4079. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4080. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4081. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4082. Plaintiffs and the California Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4083. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4084. Plaintiffs and the California Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 201:
Negligent Storage and Transportation – California

4085. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4086. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon individually and on behalf of the California Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count,

"Defendant").

4087. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4088. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4089. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4090. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4091. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and California Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4092. The latent injuries from which Plaintiffs and the California Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4093. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4094. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4095. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4096. Plaintiffs and the California Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4097. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4098. Plaintiffs and the California Amneal Prescription Medical Monitoring Class have

an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. District of Columbia

COUNT 202:
Negligence – Failure to Warn Through Proper Expiration Dates –oColumbia

4099. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4100. This cause of action is brought by Kevin Nelson individually and on behalf of the District of Columbia Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4101. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4102. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-

Specific Allegations) as to Defendant.

4103. Under District of Columbia law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

4104. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4105. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4106. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4107. The latent injuries from which Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4108. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4109. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4110. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4111. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4112. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4113. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 203:
Negligence – Failure to Warn Consumers Through the FDA – District of Columbia

4114. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4115. This cause of action is brought by Kevin Nelson individually and on behalf of the District of Columbia Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4116. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4117. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4118. Under District of Columbia law, there exists a duty owed by Defendant under failure to warn and negligence principles to follow FDA reporting requirements and notify the FDA of new information. *See Kubicki ex rel. Kubicki v. Medtronic*, No. CIV.A. 12-00734 CKK, 2013 WL 1739580, at *6–*8 (D.D.C. Mar. 21, 2013) ("[T]he Complaint alleges that Defendants knew, or should have known that technical problems were occurring in the 522 Pump subsequent to PMA approval, but never notified the FDA … despite their obligations under the federal regulations to do so. … Relatedly, the Complaint alleges failure to conduct post-approval market surveillance, including reporting all serious adverse events …. Accordingly, Plaintiffs have sufficiently pled parallel claims….") (citing, *inter alia*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232–33 (9th Cir. 2013)).

4119. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4120. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4121. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant

failed to warn anyone through any medium.

4122. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached Defendant's duty of reasonable care.

4123. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4124. The latent injuries from which Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4125. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4126. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

4127. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4128. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4129. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4130. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and

remain undiagnosed.

COUNT 204:
Negligent Product Containers – District of Columbia

4131. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4132. This cause of action is brought by Kevin Nelson individually and on behalf of the District of Columbia Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4133. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4134. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4135. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4136. Defendant breached this duty by failing to utilize containers that would minimize

the NDMA produced in its Ranitidine-Containing Products.

4137. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and District of Columbia Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4138. The latent injuries from which Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4139. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4140. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4141. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4142. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring

Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4143. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4144. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 205:
Negligent Storage and Transportation – District of Columbia

4145. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4146. This cause of action is brought by Kevin Nelson individually and on behalf of the District of Columbia Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4147. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4148. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4149. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4150. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4151. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and District of Columbia Amneal Prescription Medical Monitoring Class members have sustained a

significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4152. The latent injuries from which Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4153. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4154. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4155. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4156. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring

should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4157. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4158. Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 206:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

4159. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4160. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Joyce Taylor, Alexander Monger, Laura Monger, Michael Fesser, Michael Tomlinson, Sonia Diaz, Michael Galloway, and Karen Foster, individually and on behalf of the Florida Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4161. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4162. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4163. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4164. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

4165. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4166. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4167. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4168. The latent injuries from which Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4169. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4170. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4171. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Amneal

Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4172. Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4173. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4174. Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 207:
Medical Monitoring – Negligent Product Containers – Florida

4175. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4176. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Joyce Taylor, Michael Fesser, Michael Tomlinson, Sonia Diaz, Michael Galloway, and Karen Foster, individually and on behalf of the Florida Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4177. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4178. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4179. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4180. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4181. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4182. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4183. The latent injuries from which Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4184. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4185. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4186. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4187. Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4188. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4189. Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 208:
Medical Monitoring – Negligent Storage and Transportation – Florida

4190. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4191. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Joyce Taylor, Alexander Monger, Laura Monger, Michael Fesser, Michael Tomlinson, Sonia Diaz, Michael Galloway, and Karen Foster individually and on behalf of the Florida Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4192. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4193. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4194. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4195. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4196. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4197. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and

Florida Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4198. The latent injuries from which Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4199. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4200. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4201. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4202. Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4203. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4204. Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 209:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

4205. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4206. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Timberly Goble, individually and on behalf of the Indiana Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4207. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4208. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4209. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

4210. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4211. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4212. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Amneal Prescription

Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4213. The latent injuries from which Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4214. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4215. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4216. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4217. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay

for the medical monitoring and diagnosis of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4218. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4219. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 210:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

4220. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

4221. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Timberly Goble, individually and on behalf of the Indiana Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4222. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4223. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4224. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

4225. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4226. The FDA was reasonably expected to disseminate this information. No speculation

is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4227. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4228. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

4229. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4230. The latent injuries from which Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4231. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4232. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4233. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4234. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4235. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4236. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 211:
Negligent Product Containers – Indiana

4237. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4238. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Timberly Goble, individually and on behalf of the Indiana Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4239. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4240. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4241. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4242. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4243. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4244. The latent injuries from which Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4245. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4246. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4247. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Amneal

Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4248. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4249. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4250. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 212:
Negligent Storage and Transportation – Indiana

4251. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4252. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, and Timberly Goble, individually and on behalf of the Indiana Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4253. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4254. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4255. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4256. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4257. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer

Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Indiana Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4258. The latent injuries from which Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4259. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4260. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4261. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4262. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring

Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4263. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4264. Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 213:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

4265. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4266. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4267. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4268. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4269. Under Maryland law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

4270. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4271. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4272. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4273. The latent injuries from which Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4274. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4275. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4276. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4277. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Amneal Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4278. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4279. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 214:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

4280. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4281. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4282. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4283. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4284. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

4285. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4286. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4287. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4288. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

4289. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4290. The latent injuries from which Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

4291. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4292. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4293. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4294. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4295. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4296. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 215:
Negligent Product Containers – Maryland

4297. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4298. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4299. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4300. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4301. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4302. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4303. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4304. The latent injuries from which Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4305. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4306. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

4307. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4308. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4309. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4310. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 216:
Negligent Storage and Transportation – Maryland

4311. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4312. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4313. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4314. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4315. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4316. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

4317. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Maryland Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4318. The latent injuries from which Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4319. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4320. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4321. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4322. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4323. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4324. Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 217:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

4325. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4326. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4327. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4328. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4329. Under Missouri law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

4330. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4331. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

4332. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4333. The latent injuries from which Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4334. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4335. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4336. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4337. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class

members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4338. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4339. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 218:
Strict Products Liability – Failure to Warn Consumers Through the FDA – Missouri

4340. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4341. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4342. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4343. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4344. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

4345. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

4346. The FDA was reasonably expected to disseminate this information. No speculation

is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4347. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4348. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

4349. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4350. The latent injuries from which Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4351. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4352. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4353. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4354. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4355. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4356. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 219:
Negligent Product Containers – Missouri

4357. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4358. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4359. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4360. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4361. Under Missouri law, a manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4362. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4363. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4364. The latent injuries from which Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4365. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4366. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4367. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri

Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4368. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4369. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4370. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 220:
Negligent Storage and Transportation – Missouri

4371. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4372. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4373. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4374. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4375. Under Missouri law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4376. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4377. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer

Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Missouri Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4378. The latent injuries from which Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4379. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4380. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4381. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4382. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Amneal Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4383. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4384. Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Ohio

COUNT 221:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

4385. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4386. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4387. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4388. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4389. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

4390. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because the expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4391. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4392. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4393. The latent injuries from which Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4394. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4395. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4396. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4397. Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4398. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4399. Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 224:
Negligent Product Containers – Ohio

4400. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4401. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4402. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4403. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4404. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4405. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4406. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4407. The latent injuries from which Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4408. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4409. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4410. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4411. Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4412. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Amneal Prescription Medical Monitoring Class members in writing that they

may require frequent medical monitoring for the purpose of diagnosis.

4413. Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 225:
Negligent Storage and Transportation – Ohio

4414. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4415. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4416. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4417. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4418. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4419. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4420. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Ohio Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4421. The latent injuries from which Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4422. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4423. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4424. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4425. Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4426. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4427. Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Amneal Prescription Medical Monitoring Class members will continue to

face an unreasonable risk of injury and disability and remain undiagnosed.

9. Pennsylvania

COUNT 226:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Pennsylvania

4428. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4429. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4430. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4431. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4432. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4433. Under Pennsylvania law, a manufacturer, including Defendant, has a duty of

reasonable care to provide an adequate warning.

4434. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4435. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4436. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4437. The latent injuries from which Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4438. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4439. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4440. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4441. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4442. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4443. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring

Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 227:
Medical Monitoring – Failure to Warn Consumers Through the FDA – Pennsylvania

4444. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4445. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4446. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4447. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4448. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4449. Pennsylvania law "may impose liability for the failure to report to the FDA. …the

duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

4450. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

4451. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4452. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4453. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that

were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

4454. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4455. The latent injuries from which Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4456. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4457. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4458. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4459. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4460. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4461. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 228:
Medical Monitoring – Negligent Product Containers – Pennsylvania

4462. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4463. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4464. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4465. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4466. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4467. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4468. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4469. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Pennsylvania Amneal Prescription Medical Monitoring Class members have sustained a significantly increased

risk of developing serious and potentially Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4470. The latent injuries from which Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4471. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4472. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4473. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4474. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Amneal

Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4475. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4476. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 229:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

4477. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

4478. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4479. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4480. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4481. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4482. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4483. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4484. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Pennsylvania Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4485. The latent injuries from which Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4486. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4487. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4488. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4489. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4490. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4491. Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. Utah

COUNT 230:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Utah

4492. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4493. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4494. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4495. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4496. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4497. Under Utah law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

4498. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4499. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4500. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Utah Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing

serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4501. The latent injuries from which Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4502. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4503. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4504. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4505. Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Amneal Prescription Medical

Monitoring Class members as frequently and appropriately as necessary.

4506. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4507. Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 231:
Medical Monitoring – Negligent Product Containers – Utah

4508. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4509. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4510. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4511. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4512. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4513. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4514. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4515. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4516. The latent injuries from which Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4517. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4518. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4519. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4520. Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4521. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Amneal Prescription Medical Monitoring Class members in writing that they

may require frequent medical monitoring for the purpose of diagnosis.

4522. Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 232:
Medical Monitoring – Negligent Storage and Transportation – Utah

4523. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4524. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4525. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4526. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4527. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4528. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4529. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4530. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Utah Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4531. The latent injuries from which Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4532. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4533. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4534. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4535. Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4536. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4537. Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. West Virginia

COUNT 233:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

4538. Plaintiffs incorporate by reference each allegation set forth in paragraphs 41–153 (describing Generic Manufacturer Defendants) and 432–37 (describing the regulatory framework for generics) and paragraphs 322–42 (describing the recall of ranitidine), 385–97 (describing the breakdown of ranitidine before ingestion), 405–08 (describing Defendant's knowledge), 409–31 (describing the regulatory framework for drug manufacturers), and 455–66 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4539. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4540. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4541. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4542. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4543. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4544. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

4545. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4546. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4547. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4548. The latent injuries from which Plaintiffs and the West Virginia Amneal Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4549. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4550. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4551. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4552. Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4553. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4554. Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 234:
Medical Monitoring – Negligent Product Containers – West Virginia

4555. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4556. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Amneal Prescription Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4557. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4558. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4559. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4560. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4561. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4562. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4563. The latent injuries from which Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4564. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4565. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4566. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4567. Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4568. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4569. Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class

have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 235:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

4570. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4571. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

4572. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Amneal Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Amneal (for the purposes of this Count, "Defendant").

4573. The allegations in this Count apply to Amneal during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4574. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4575. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4576. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4577. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4578. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and West Virginia Amneal Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4579. The latent injuries from which Plaintiffs and the West Virginia Amneal Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4580. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4581. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4582. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4583. Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4584. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Amneal Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4585. Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Amneal Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

G. CAUSES OF ACTION AGAINST DEFENDANT DR. REDDY'S WITH RESPECT TO PRESCRIPTION RANITIDINE

4586. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's with respect to prescription ranitidine on behalf of themselves and their respective State Dr. Reddy's Prescription Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA

Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Antrenise Campbell	MO
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

1. Arizona

COUNT 236:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

4587. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4588. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4589. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4590. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4591. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

4592. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4593. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4594. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4595. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4596. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4597. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4598. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4599. Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4600. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4601. Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 237:
Negligent Product Containers – Arizona

4602. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4603. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4604. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4605. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4606. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4607. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4608. As a direct and proximate result of this failure, excessive levels of NDMA built up

in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4609. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4610. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4611. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4612. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4613. Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4614. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4615. Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 238:
Negligent Storage and Transportation – Arizona

4616. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4617. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4618. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4619. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4620. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4621. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4622. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Arizona Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4623. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4624. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4625. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4626. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4627. Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4628. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4629. Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 239:
Negligence – Failure to Warn Through Proper Expiration Dates – California

4630. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4631. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Dr. Reddy's Prescription Medical Monitoring

Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4632. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4633. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4634. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

4635. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4636. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4637. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4638. The latent injuries from which Plaintiffs and the California Dr. Reddy's

Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4639. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4640. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4641. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4642. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4643. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4644. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 240:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

4645. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4646. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia

Aragon, individually and on behalf of the California Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4647. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4648. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4649. Under California law, manufacturers (including Defendant) bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

4650. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4651. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4652. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer

risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

4653. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

4654. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4655. The latent injuries from which Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4656. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4657. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

4658. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4659. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4660. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4661. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and

remain undiagnosed.

COUNT 241:
Negligent Product Containers – California

4662. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4663. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4664. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4665. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4666. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4667. Defendant breached this duty by failing to utilize containers that would minimize

the NDMA produced in its Ranitidine-Containing Products.

4668. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4669. The latent injuries from which Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4670. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4671. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4672. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4673. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class

members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4674. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4675. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 242:
Negligent Storage and Transportation – California

4676. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4677. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4678. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4679. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4680. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4681. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4682. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed.

Plaintiffs and California Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4683. The latent injuries from which Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4684. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4685. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4686. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4687. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Prescription

Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4688. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4689. Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. District of Columbia

COUNT 243:
Negligence – Failure to Warn Through Proper Expiration Dates – District of Columbia

4690. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4691. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4692. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4693. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4694. Under District of Columbia law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

4695. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4696. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

4697. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4698. The latent injuries from which Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4699. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4700. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4701. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4702. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical

Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4703. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4704. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 244:
Negligence – Failure to Warn Consumers Through the FDA – District of Columbia

4705. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4706. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4707. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4708. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4709. Under District of Columbia law, there exists a duty owed by Defendant under failure to warn and negligence principles to follow FDA reporting requirements and notify the FDA of new information. *See Kubicki ex rel. Kubicki v. Medtronic*, No. CIV.A. 12-00734 CKK, 2013 WL 1739580, at *6–*8 (D.D.C. Mar. 21, 2013) ("[T]he Complaint alleges that Defendants knew, or should have known that technical problems were occurring in the 522 Pump subsequent to PMA approval, but never notified the FDA … despite their obligations under the federal regulations to do so. … Relatedly, the Complaint alleges failure to conduct post-approval market surveillance, including reporting all serious adverse events …. Accordingly, Plaintiffs have sufficiently pled parallel claims….") (citing, *inter alia*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224,

1232–33 (9th Cir. 2013)).

4710. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4711. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4712. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

4713. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached Defendant's duty of reasonable care.

4714. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4715. The latent injuries from which Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4716. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4717. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4718. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4719. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4720. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4721. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 245:
Negligent Product Containers – District of Columbia

4722. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4723. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4724. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4725. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4726. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4727. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4728. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4729. The latent injuries from which Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject

Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4730. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4731. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4732. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4733. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4734. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4735. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 246:
Negligent Storage and Transportation – District of Columbia

4736. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4737. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4738. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4739. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4740. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4741. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4742. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4743. The latent injuries from which Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4744. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4745. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4746. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4747. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4748. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4749. Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical

Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 247:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

4750. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4751. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4752. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4753. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4754. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4755. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

4756. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4757. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4758. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4759. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4760. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4761. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4762. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4763. Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4764. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4765. Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 248:
Medical Monitoring – Negligent Product Containers – Florida

4766. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4767. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Dr. Reddy's

Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4768. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4769. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4770. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4771. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4772. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4773. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4774. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

4775. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4776. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4777. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4778. Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4779. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4780. Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 249:
Medical Monitoring – Negligent Storage and Transportation – Florida

4781. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4782. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4783. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

4784. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4785. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

4786. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4787. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4788. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Florida Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4789. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4790. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4791. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4792. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4793. Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4794. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4795. Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class have

an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 250:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

4796. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4797. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4798. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4799. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4800. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

4801. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4802. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4803. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4804. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4805. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4806. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4807. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4808. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4809. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4810. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class have

an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 251:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

4811. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4812. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4813. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4814. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-

Specific Allegations) as to Defendant.

4815. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

4816. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4817. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4818. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4819. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that

were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

4820. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4821. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4822. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4823. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4824. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4825. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4826. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4827. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 252:
Negligent Product Containers – Indiana

4828. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4829. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4830. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4831. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4832. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4833. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4834. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4835. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4836. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4837. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4838. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4839. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4840. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4841. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 253:
Negligent Storage and Transportation – Indiana

4842. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4843. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Dr. Reddy's Prescription Medical

Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4844. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4845. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4846. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4847. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4848. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Indiana Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4849. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4850. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4851. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4852. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4853. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4854. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's Prescription Medical Monitoring Class members in writing that

they may require frequent medical monitoring for the purpose of diagnosis.

4855. Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 254:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

4856. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4857. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4858. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4859. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4860. Under Maryland law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

4861. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4862. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4863. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4864. The latent injuries from which Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4865. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4866. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4867. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4868. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4869. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Dr. Reddy's Prescription Medical Monitoring Class members in writing

that they may require frequent medical monitoring for the purpose of diagnosis.

4870. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 255:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

4871. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4872. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4873. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4874. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4875. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

4876. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

4877. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4878. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4879. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

4880. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4881. The latent injuries from which Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4882. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4883. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

4884. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4885. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4886. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4887. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 256:
Negligent Product Containers – Maryland

4888. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4889. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4890. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4891. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4892. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4893. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4894. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4895. The latent injuries from which Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4896. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4897. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4898. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4899. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program

which will facilitate the diagnoses of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4900. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4901. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 257:
Negligent Storage and Transportation – Maryland

4902. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4903. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4904. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4905. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4906. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4907. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4908. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Maryland Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers

and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4909. The latent injuries from which Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4910. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4911. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4912. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4913. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Dr. Reddy's

Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4914. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4915. Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 258:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

4916. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4917. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4918. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4919. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4920. Under Missouri law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

4921. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4922. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4923. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4924. The latent injuries from which Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4925. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4926. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4927. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4928. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Dr. Reddy's

Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4929. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4930. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 259:
Strict Products Liability – Failure to Warn Consumers Through the FDA – Missouri

4931. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

4932. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4933. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4934. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

4935. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

4936. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

4937. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

4938. Because federal law requires generic drug labels to largely match branded drug

labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

4939. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

4940. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4941. The latent injuries from which Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4942. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4943. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4944. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4945. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4946. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4947. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring

Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 260:
Negligent Product Containers – Missouri

4948. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4949. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4950. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4951. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4952. Under Missouri law, a manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4953. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4954. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4955. The latent injuries from which Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4956. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4957. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4958. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4959. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4960. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4961. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 261:
Negligent Storage and Transportation – Missouri

4962. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4963. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4964. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4965. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

4966. Under Missouri law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

4967. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

4968. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed.

Plaintiffs and Missouri Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4969. The latent injuries from which Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4970. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4971. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4972. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4973. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4974. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4975. Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Ohio

COUNT 262:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

4976. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4977. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4978. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4979. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

4980. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

4981. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because the expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

4982. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

4983. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4984. The latent injuries from which Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4985. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

4986. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

4987. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4988. Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program

which will facilitate the diagnoses of Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

4989. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4990. Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 263:
Negligent Product Containers – Ohio

4991. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

4992. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

4993. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

4994. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

4995. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

4996. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

4997. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4998. The latent injuries from which Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4999. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5000. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5001. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5002. Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5003. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5004. Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 264:
Negligent Storage and Transportation – Ohio

5005. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5006. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5007. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

5008. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5009. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5010. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5011. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Ohio Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5012. The latent injuries from which Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5013. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5014. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5015. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5016. Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5017. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5018. Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Pennsylvania

COUNT 265:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Pennsylvania

5019. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5020. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5021. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5022. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5023. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5024. Under Pennsylvania law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning.

5025. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5026. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5027. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5028. The latent injuries from which Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5029. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5030. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5031. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5032. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5033. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5034. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class

have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 266:
Medical Monitoring – Failure to Warn Consumers Through the FDA – Pennsylvania

5035. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5036. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5037. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5038. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5039. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5040. Pennsylvania law "may impose liability for the failure to report to the FDA. …the duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

5041. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

5042. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5043. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather

than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

5044. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

5045. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5046. The latent injuries from which Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5047. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5048. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5049. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5050. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5051. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5052. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical

Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 267:
Medical Monitoring – Negligent Product Containers – Pennsylvania

5053. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5054. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5055. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5056. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5057. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5058. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5059. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5060. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5061. The latent injuries from which Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5062. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5063. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5064. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania

Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5065. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5066. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5067. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 268:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

5068. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5069. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5070. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5071. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5072. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5073. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5074. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5075. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5076. The latent injuries from which Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5077. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5078. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5079. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5080. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5081. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5082. Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. Utah

COUNT 269:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Utah

5083. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5084. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5085. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5086. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5087. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5088. Under Utah law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it

knows or should have known about.

5089. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5090. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5091. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Utah Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5092. The latent injuries from which Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5093. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5094. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5095. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5096. Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5097. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5098. Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members will continue

to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 270:
Medical Monitoring – Negligent Product Containers – Utah

5099. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5100. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5101. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5102. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5103. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5104. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5105. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5106. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5107. The latent injuries from which Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5108. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5109. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5110. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5111. Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5112. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5113. Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 271:
Medical Monitoring – Negligent Storage and Transportation – Utah

5114. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5115. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5116. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5117. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5118. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5119. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5120. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5121. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed.

Plaintiffs and Utah Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5122. The latent injuries from which Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5123. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5124. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5125. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5126. Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Dr. Reddy's Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5127. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5128. Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. West Virginia

COUNT 272:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

5129. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5130. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5131. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5132. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5133. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5134. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

5135. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5136. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5137. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5138. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5139. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5140. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5141. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5142. Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring

program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5143. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5144. Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 273:
Medical Monitoring – Negligent Product Containers – West Virginia

5145. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5146. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5147. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5148. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5149. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5150. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5151. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5152. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and

will suffer economic losses and expenses associated with ongoing medical monitoring.

5153. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5154. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5155. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5156. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5157. Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and

appropriately as necessary.

5158. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5159. Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 274:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

5160. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

5161. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

5162. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5163. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5164. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5165. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5166. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5167. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and West Virginia Dr. Reddy's Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5168. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5169. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5170. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5171. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5172. Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5173. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5174. Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

H. CAUSES OF ACTION AGAINST DEFENDANT GLENMARK WITH RESPECT TO PRESCRIPTION RANITIDINE

5175. Plaintiffs identified in the table below bring claims against Defendant Glenmark with respect to prescription ranitidine on behalf of themselves and their respective State Glenmark Prescription Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA

Plaintiff Name	**State of Usage**
Virginia Aragon	CA
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT

Plaintiff Name	State of Usage
Mynetta Hastings	WV

1. Arizona

COUNT 275:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

5176. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5177. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5178. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5179. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5180. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light

of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

5181. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5182. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5183. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5184. The latent injuries from which Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5185. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

5186. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5187. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5188. Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5189. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5190. Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 276:
Negligent Product Containers – Arizona

5191. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5192. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5193. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5194. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5195. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5196. Defendant breached this duty by failing to utilize containers that would minimize

the NDMA produced in its Ranitidine-Containing Products.

5197. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5198. The latent injuries from which Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5199. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5200. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5201. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5202. Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class

members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5203. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5204. Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 277:
Negligent Storage and Transportation – Arizona

5205. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5206. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5207. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5208. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5209. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5210. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5211. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Arizona Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5212. The latent injuries from which Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5213. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5214. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5215. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5216. Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5217. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5218. Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 278:
Negligence – Failure to Warn Through Proper Expiration Dates – California

5219. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5220. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia

Aragon, individually and on behalf of the California Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5221. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5222. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5223. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

5224. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5225. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5226. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5227. The latent injuries from which Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5228. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5229. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5230. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5231. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5232. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5233. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 279:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

5234. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5235. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Glenmark Prescription Medical Monitoring

Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5236. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5237. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5238. Under California law, manufacturers (including Defendant) bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

5239. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

5240. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5241. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate

information to the public, Defendant failed to warn anyone through any medium.

5242. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

5243. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5244. The latent injuries from which Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5245. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5246. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5247. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5248. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5249. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5250. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 280:
Negligent Product Containers – California

5251. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5252. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5253. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5254. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5255. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5256. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5257. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California

Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5258. The latent injuries from which Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5259. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5260. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5261. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5262. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5263. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5264. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 281:
Negligent Storage and Transportation – California

5265. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

5266. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5267. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5268. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5269. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5270. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5271. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and California Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5272. The latent injuries from which Plaintiffs and the California Glenmark Prescription

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5273. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5274. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5275. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5276. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5277. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5278. Plaintiffs and the California Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. District of Columbia

COUNT 282:
Negligence – Failure to Warn Through Proper Expiration Dates – District of Columbia

5279. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5280. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Glenmark Prescription Medical Monitoring Class (for the purposes of this

Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5281. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5282. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5283. Under District of Columbia law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

5284. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5285. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5286. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5287. The latent injuries from which Plaintiffs and the District of Columbia Glenmark

Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5288. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5289. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5290. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5291. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5292. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5293. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 283:
Negligence – Failure to Warn Consumers Through the FDA – District of Columbia

5294. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5295. This cause of action is brought by Kevin Nelson, individually and on behalf of the

District of Columbia Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5296. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5297. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5298. Under District of Columbia law, there exists a duty owed by Defendant under failure to warn and negligence principles to follow FDA reporting requirements and notify the FDA of new information. *See Kubicki ex rel. Kubicki v. Medtronic*, No. CIV.A. 12-00734 CKK, 2013 WL 1739580, at *6–*8 (D.D.C. Mar. 21, 2013) ("[T]he Complaint alleges that Defendants knew, or should have known that technical problems were occurring in the 522 Pump subsequent to PMA approval, but never notified the FDA … despite their obligations under the federal regulations to do so. … Relatedly, the Complaint alleges failure to conduct post-approval market surveillance, including reporting all serious adverse events …. Accordingly, Plaintiffs have sufficiently pled parallel claims….") (citing, *inter alia*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232–33 (9th Cir. 2013)).

5299. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

5300. The FDA was reasonably expected to disseminate this information. No speculation

is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5301. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

5302. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached Defendant's duty of reasonable care.

5303. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5304. The latent injuries from which Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5305. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5306. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5307. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5308. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5309. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5310. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring

Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 284:
Negligent Product Containers – District Of Columbia

5311. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5312. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5313. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5314. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to Defendant.

5315. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5316. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5317. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and District of Columbia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5318. The latent injuries from which Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5319. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5320. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5321. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5322. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5323. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5324. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Glenmark Prescription Medical

Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 285:
Negligent Storage and Transportation – District of Columbia

5325. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5326. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5327. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5328. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5329. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5330. Defendant breached this duty by failing to implement or enforce policies to ensure

Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5331. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and District of Columbia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5332. The latent injuries from which Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5333. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5334. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5335. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of

Columbia Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5336. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5337. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5338. Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 286:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

5339. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5340. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5341. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5342. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5343. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5344. Under Florida law, pharmaceutical manufacturers, including Defendant, have a

duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

5345. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5346. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5347. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5348. The latent injuries from which Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5349. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5350. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5351. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5352. Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5353. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5354. Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 287:
Medical Monitoring – Negligent Product Containers – Florida

5355. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5356. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5357. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5358. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5359. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5360. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5361. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5362. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5363. The latent injuries from which Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5364. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5365. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

5366. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5367. Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5368. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5369. Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 288:
Medical Monitoring – Negligent Storage and Transportation – Florida

5370. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5371. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5372. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5373. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5374. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5375. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty

to exercise reasonable care in transporting and storing products.

5376. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5377. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Florida Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5378. The latent injuries from which Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5379. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5380. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5381. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5382. Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5383. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5384. Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 289:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

5385. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5386. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5387. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5388. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5389. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

5390. Defendant breached this duty for its Ranitidine-Containing Products. The

expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5391. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5392. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5393. The latent injuries from which Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5394. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5395. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

5396. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5397. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5398. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5399. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 290:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

5400. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5401. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5402. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5403. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5404. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed

by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

5405. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

5406. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5407. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

5408. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

5409. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5410. The latent injuries from which Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5411. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5412. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5413. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5414. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Glenmark

Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5415. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5416. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 291:
Negligent Product Containers – Indiana

5417. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5418. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5419. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5420. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5421. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5422. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5423. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5424. The latent injuries from which Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

5425. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5426. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5427. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5428. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5429. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5430. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 292:
Negligent Storage and Transportation – Indiana

5431. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5432. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5433. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5434. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5435. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5436. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5437. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Indiana Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5438. The latent injuries from which Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5439. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5440. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5441. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5442. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5443. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5444. Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Glenmark Prescription Medical Monitoring Class members will

continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 293:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

5445. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5446. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5447. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5448. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5449. Under Maryland law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known

about.

5450. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5451. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5452. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5453. The latent injuries from which Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5454. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5455. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5456. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5457. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5458. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5459. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will

continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 294:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

5460. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5461. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5462. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5463. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5464. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends

beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

5465. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

5466. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5467. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

5468. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

5469. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5470. The latent injuries from which Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5471. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5472. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5473. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5474. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Glenmark Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5475. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5476. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 295:
Negligent Product Containers – Maryland

5477. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5478. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5479. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5480. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5481. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5482. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5483. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5484. The latent injuries from which Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5485. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5486. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5487. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5488. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5489. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Maryland Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5490. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 296:
Negligent Storage and Transportation – Maryland

5491. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5492. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5493. The allegations in this Count apply to Glenmark during the time period in which it

was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5494. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5495. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5496. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5497. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Maryland Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5498. The latent injuries from which Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5499. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5500. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5501. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5502. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5503. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5504. Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk

of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 297:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

5505. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5506. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5507. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5508. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-

Specific Allegations) as to Defendant.

5509. Under Missouri law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

5510. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5511. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5512. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5513. The latent injuries from which Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5514. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5515. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5516. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5517. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5518. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5519. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products.

Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 298:
Strict Products Liability – Failure to Warn Consumers Through the FDA – Missouri

5520. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5521. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5522. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5523. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5524. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause

of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements ….” *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

5525. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

5526. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5527. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

5528. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

5529. As a direct and proximate result of Defendant’s failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5530. The latent injuries from which Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5531. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5532. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5533. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5534. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Glenmark

Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5535. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5536. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 299:
Negligent Product Containers – Missouri

5537. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5538. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5539. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5540. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5541. Under Missouri law, a manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5542. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5543. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5544. The latent injuries from which Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

5545. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5546. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5547. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5548. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5549. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5550. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 300:
Negligent Storage and Transportation – Missouri

5551. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5552. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5553. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5554. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5555. Under Missouri law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5556. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5557. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Missouri Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5558. The latent injuries from which Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5559. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5560. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5561. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5562. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5563. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5564. Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Glenmark Prescription Medical Monitoring Class members will

continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Ohio

COUNT 301:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

5565. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5566. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5567. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5568. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5569. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

5570. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5571. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5572. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5573. The latent injuries from which Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5574. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5575. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5576. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5577. Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5578. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5579. Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members will continue

to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 302:
Negligent Product Containers – Ohio

5580. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5581. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5582. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5583. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5584. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5585. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5586. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5587. The latent injuries from which Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5588. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5589. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5590. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5591. Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5592. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5593. Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 303:
Negligent Storage and Transportation – Ohio

5594. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5595. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5596. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5597. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5598. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5599. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Ohio Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5600. The latent injuries from which Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5601. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5602. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5603. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5604. Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5605. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5606. Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Pennsylvania

COUNT 304:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Pennsylvania

5607. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5608. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5609. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5610. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5611. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5612. Under Pennsylvania law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning.

5613. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5614. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5615. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5616. The latent injuries from which Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant

treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5617. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5618. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5619. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5620. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5621. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5622. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 305:
Medical Monitoring – Failure to Warn Consumers Through the FDA – Pennsylvania

5623. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5624. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Glenmark Prescription Medical Monitoring Class

(for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5625. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5626. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5627. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5628. Pennsylvania law "may impose liability for the failure to report to the FDA. …the duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

5629. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

5630. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5631. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

5632. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

5633. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5634. The latent injuries from which Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5635. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5636. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5637. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5638. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5639. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5640. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 306:
Medical Monitoring – Negligent Product Containers – Pennsylvania

5641. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5642. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5643. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

5644. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5645. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5646. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5647. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5648. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Pennsylvania Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5649. The latent injuries from which Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5650. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

5651. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5652. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5653. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5654. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5655. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing

Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 307:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

5656. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5657. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5658. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5659. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5660. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5661. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5662. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5663. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Pennsylvania Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5664. The latent injuries from which Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5665. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

5666. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5667. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5668. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5669. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5670. Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing

Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. Utah

COUNT 308:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Utah

5671. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5672. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5673. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5674. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5675. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5676. Under Utah law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

5677. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5678. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5679. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Utah Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5680. The latent injuries from which Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5681. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5682. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5683. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5684. Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5685. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5686. Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 309:
Medical Monitoring – Negligent Product Containers – Utah

5687. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5688. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5689. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5690. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5691. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5692. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5693. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5694. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5695. The latent injuries from which Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5696. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5697. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

5698. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5699. Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5700. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5701. Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 310:
Medical Monitoring – Negligent Storage and Transportation – Utah

5702. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5703. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5704. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5705. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5706. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5707. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5708. Defendant breached this duty by failing to implement or enforce policies to ensure

Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5709. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Utah Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5710. The latent injuries from which Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5711. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5712. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5713. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

5714. Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5715. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5716. Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. West Virginia

COUNT 311:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

5717. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5718. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5719. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5720. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5721. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5722. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

5723. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5724. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5725. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5726. The latent injuries from which Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5727. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5728. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5729. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia

Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5730. Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5731. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5732. Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 312:
Medical Monitoring – Negligent Product Containers – West Virginia

5733. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5734. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5735. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5736. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5737. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5738. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5739. Defendant breached this duty by failing to utilize containers that would minimize

the NDMA produced in its Ranitidine-Containing Products.

5740. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5741. The latent injuries from which Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5742. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5743. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5744. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5745. Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class

members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5746. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5747. Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 313:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

5748. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5749. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Glenmark Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Glenmark (for the purposes of this Count, "Defendant").

5750. The allegations in this Count apply to Glenmark during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5751. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5752. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5753. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5754. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5755. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer

Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and West Virginia Glenmark Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5756. The latent injuries from which Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5757. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5758. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5759. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5760. Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Glenmark Prescription

Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5761. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Glenmark Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5762. Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Glenmark Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

I. CAUSES OF ACTION AGAINST DEFENDANT SANDOZ WITH RESPECT TO PRESCRIPTION RANITIDINE

5763. Plaintiffs identified in the table below bring claims against Defendant Sandoz with respect to prescription ranitidine on behalf of themselves and their respective State Sandoz Prescription Medical Monitoring Classes under the laws of their respective states of usage. Each

Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Antrenise Campbell	MO
Brenda Newcomb	MO

Plaintiff Name	State of Usage
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH; FL
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

1. Arizona

COUNT 314:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

5764. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5765. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5766. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5767. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5768. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

5769. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5770. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5771. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5772. The latent injuries from which Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5773. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5774. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5775. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5776. Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5777. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5778. Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 315:
Negligent Product Containers – Arizona

5779. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5780. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5781. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5782. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5783. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5784. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5785. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5786. The latent injuries from which Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5787. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5788. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5789. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5790. Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5791. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5792. Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 316:
Negligent Storage and Transportation – Arizona

5793. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5794. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5795. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5796. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5797. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5798. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5799. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Arizona Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5800. The latent injuries from which Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5801. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5802. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5803. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5804. Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5805. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5806. Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 317:
Negligence – Failure to Warn Through Proper Expiration Dates – California

5807. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5808. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5809. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5810. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5811. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

5812. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5813. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5814. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5815. The latent injuries from which Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5816. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5817. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5818. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5819. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5820. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5821. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 318:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

5822. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5823. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5824. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5825. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5826. Under California law, manufacturers (including Defendant) bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes

"a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

5827. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

5828. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5829. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

5830. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

5831. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5832. The latent injuries from which Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5833. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5834. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5835. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5836. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5837. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5838. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 319:
Negligent Product Containers – California

5839. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

5840. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5841. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5842. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5843. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5844. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5845. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5846. The latent injuries from which Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5847. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5848. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5849. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5850. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5851. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all California Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5852. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 320:
Negligent Storage and Transportation – California

5853. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5854. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5855. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5856. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5857. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5858. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5859. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and California Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5860. The latent injuries from which Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5861. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5862. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5863. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5864. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5865. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5866. Plaintiffs and the California Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 321:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

5867. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5868. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5869. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5870. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5871. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5872. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

5873. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5874. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5875. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Colorado Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5876. The latent injuries from which Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5877. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5878. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5879. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5880. Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5881. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Colorado Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5882. Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 322:
Medical Monitoring – Negligent Product Containers – Colorado

5883. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5884. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5885. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5886. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5887. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5888. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5889. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5890. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Colorado Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5891. The latent injuries from which Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5892. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5893. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5894. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5895. Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5896. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5897. Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 323:
Medical Monitoring – Negligent Storage and Transportation – Colorado

5898. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5899. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5900. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5901. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-

Specific Allegations) as to Defendant.

5902. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5903. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5904. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5905. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Colorado Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5906. The latent injuries from which Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5907. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5908. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5909. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5910. Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5911. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5912. Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. District of Columbia

COUNT 324:
Negligence – Failure to Warn Through Proper Expiration Dates – District of Columbia

5913. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5914. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5915. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5916. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5917. Under District of Columbia law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

5918. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5919. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5920. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5921. The latent injuries from which Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5922. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5923. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5924. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5925. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5926. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5927. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 325:
Negligence – Failure to Warn Consumers Through the FDA – District of Columbia

5928. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5929. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5930. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5931. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

5932. Under District of Columbia law, there exists a duty owed by Defendant under failure to warn and negligence principles to follow FDA reporting requirements and notify the FDA of new information. *See Kubicki ex rel. Kubicki v. Medtronic*, No. CIV.A. 12-00734 CKK, 2013 WL 1739580, at *6–*8 (D.D.C. Mar. 21, 2013) ("[T]he Complaint alleges that Defendants knew, or should have known that technical problems were occurring in the 522 Pump subsequent to PMA approval, but never notified the FDA … despite their obligations under the federal regulations to do so. … Relatedly, the Complaint alleges failure to conduct post-approval market surveillance, including reporting all serious adverse events …. Accordingly, Plaintiffs have sufficiently pled parallel claims….") (citing, *inter alia*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232–33 (9th Cir. 2013)).

5933. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

5934. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

5935. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather

than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

5936. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached Defendant's duty of reasonable care.

5937. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5938. The latent injuries from which Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5939. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5940. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5941. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5942. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5943. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5944. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or

established by the Court, Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 326:
Negligent Product Containers – District of Columbia

5945. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5946. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5947. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5948. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5949. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5950. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5951. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and District of Columbia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5952. The latent injuries from which Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5953. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5954. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5955. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5956. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5957. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5958. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 327:
Negligent Storage and Transportation – District of Columbia

5959. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5960. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5961. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5962. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

5963. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

5964. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

5965. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and District of Columbia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5966. The latent injuries from which Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5967. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5968. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5969. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5970. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5971. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5972. Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Florida

COUNT 328:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

5973. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5974. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Galloway, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5975. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5976. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

5977. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5978. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light

of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

5979. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

5980. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

5981. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5982. The latent injuries from which Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5983. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5984. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

5985. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5986. Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

5987. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5988. Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 329:
Medical Monitoring – Negligent Product Containers – Florida

5989. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

5990. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Galloway, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

5991. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

5992. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

5993. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

5994. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

5995. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

5996. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5997. The latent injuries from which Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5998. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

5999. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6000. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6001. Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6002. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6003. Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 330:
Medical Monitoring – Negligent Storage and Transportation – Florida

6004. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6005. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Galloway, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6006. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6007. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6008. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6009. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6010. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6011. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Florida Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6012. The latent injuries from which Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6013. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6014. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6015. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6016. Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6017. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6018. Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Indiana

COUNT 331:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

6019. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6020. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6021. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6022. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6023. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

6024. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6025. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6026. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6027. The latent injuries from which Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6028. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6029. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6030. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6031. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6032. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6033. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 332:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

6034. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6035. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6036. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6037. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6038. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

6039. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

6040. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6041. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6042. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that

were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

6043. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6044. The latent injuries from which Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6045. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6046. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6047. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6048. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6049. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6050. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 333:
Negligent Product Containers – Indiana

6051. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6052. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6053. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6054. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6055. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6056. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6057. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6058. The latent injuries from which Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6059. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6060. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6061. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6062. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6063. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6064. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 334:
Negligent Storage and Transportation – Indiana

6065. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6066. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6067. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6068. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6069. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6070. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6071. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Indiana Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6072. The latent injuries from which Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6073. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6074. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6075. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6076. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6077. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6078. Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Maryland

COUNT 335:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

6079. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6080. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6081. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6082. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6083. Under Maryland law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

6084. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6085. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6086. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6087. The latent injuries from which Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6088. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6089. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6090. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6091. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6092. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Maryland Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6093. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 336:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

6094. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6095. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6096. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6097. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6098. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

6099. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

6100. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6101. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather

than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6102. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

6103. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6104. The latent injuries from which Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6105. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6106. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6107. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6108. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6109. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6110. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 337:
Negligent Product Containers – Maryland

6111. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6112. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6113. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6114. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6115. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6116. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6117. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6118. The latent injuries from which Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6119. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6120. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6121. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6122. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6123. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6124. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 338:
Negligent Storage and Transportation – Maryland

6125. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6126. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6127. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6128. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6129. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6130. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6131. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Maryland Sandoz Prescription Medical Monitoring Class members have sustained a significantly

increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6132. The latent injuries from which Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6133. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6134. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6135. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6136. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6137. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6138. Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Missouri

COUNT 339:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

6139. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6140. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6141. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6142. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6143. Under Missouri law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

6144. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6145. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6146. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6147. The latent injuries from which Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6148. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6149. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6150. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6151. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6152. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6153. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 340:
Strict Products Liability – Failure to Warn Consumers Through the FDA – Missouri

6154. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

6155. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron , individually and on behalf of the Missouri Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6156. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6157. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6158. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

6159. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

6160. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6161. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6162. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

6163. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6164. The latent injuries from which Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6165. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6166. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6167. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6168. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6169. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6170. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 341:
Negligent Product Containers – Missouri

6171. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6172. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6173. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6174. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6175. Under Missouri law, a manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6176. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6177. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6178. The latent injuries from which Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6179. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6180. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6181. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6182. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6183. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6184. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 342:
Negligent Storage and Transportation – Missouri

6185. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6186. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6187. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6188. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6189. Under Missouri law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6190. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6191. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Missouri Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6192. The latent injuries from which Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6193. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6194. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6195. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6196. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6197. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6198. Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Ohio

COUNT 343:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

6199. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6200. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6201. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6202. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6203. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

6204. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6205. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6206. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6207. The latent injuries from which Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6208. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6209. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6210. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6211. Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6212. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6213. Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 344:
Negligent Product Containers – Ohio

6214. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6215. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6216. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6217. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6218. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6219. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6220. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6221. The latent injuries from which Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6222. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6223. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6224. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6225. Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6226. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6227. Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 345:
Negligent Storage and Transportation – Ohio

6228. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6229. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6230. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6231. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6232. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6233. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6234. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Ohio Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6235. The latent injuries from which Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6236. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6237. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6238. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6239. Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6240. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6241. Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. Pennsylvania

COUNT 346:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Pennsylvania

6242. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6243. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6244. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6245. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6246. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6247. Under Pennsylvania law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning.

6248. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6249. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6250. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6251. The latent injuries from which Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6252. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6253. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6254. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6255. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6256. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6257. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 347:
Medical Monitoring – Failure to Warn Consumers Through the FDA – Pennsylvania

6258. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6259. This cause of action is brought by Felicia Ball and Joyce Guerrieri , individually and on behalf of the Pennsylvania Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6260. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6261. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6262. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6263. Pennsylvania law "may impose liability for the failure to report to the FDA. …the duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

6264. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

6265. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6266. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6267. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

6268. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6269. The latent injuries from which Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6270. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6271. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6272. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6273. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6274. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6275. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 348:
Medical Monitoring – Negligent Product Containers – Pennsylvania

6276. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6277. This cause of action is brought by Felicia Ball and Joyce Guerrieri , individually and on behalf of the Pennsylvania Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6278. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6279. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6280. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6281. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6282. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6283. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Pennsylvania Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6284. The latent injuries from which Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6285. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6286. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6287. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6288. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6289. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6290. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring

Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 349:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

6291. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6292. This cause of action is brought by Felicia Ball and Joyce Guerrieri , individually and on behalf of the Pennsylvania Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6293. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6294. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6295. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6296. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6297. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6298. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Pennsylvania Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6299. The latent injuries from which Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6300. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6301. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6302. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6303. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6304. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6305. Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Sandoz Prescription Medical Monitoring

Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. Utah

COUNT 350:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Utah

6306. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6307. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6308. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6309. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6310. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6311. Under Utah law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

6312. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6313. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6314. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Utah Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6315. The latent injuries from which Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6316. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6317. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6318. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6319. Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6320. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6321. Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 351:
Medical Monitoring – Negligent Product Containers – Utah

6322. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6323. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6324. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6325. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6326. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6327. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6328. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6329. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6330. The latent injuries from which Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6331. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6332. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6333. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6334. Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6335. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6336. Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 352:
Medical Monitoring – Negligent Storage and Transportation – Utah

6337. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6338. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6339. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6340. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6341. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6342. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6343. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6344. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Utah Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6345. The latent injuries from which Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6346. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6347. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6348. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6349. Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6350. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6351. Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

12. West Virginia

COUNT 353:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

6352. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6353. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6354. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6355. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6356. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6357. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

6358. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6359. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6360. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6361. The latent injuries from which Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6362. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6363. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6364. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6365. Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6366. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6367. Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 354:
Medical Monitoring – Negligent Product Containers – West Virginia

6368. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6369. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6370. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6371. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6372. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6373. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6374. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6375. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6376. The latent injuries from which Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6377. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6378. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6379. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6380. Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6381. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6382. Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 355:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

6383. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6384. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Sandoz Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Sandoz (for the purposes of this Count, "Defendant").

6385. The allegations in this Count apply to Sandoz during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6386. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6387. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6388. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6389. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6390. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer

Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and West Virginia Sandoz Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6391. The latent injuries from which Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6392. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6393. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6394. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6395. Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Sandoz Prescription Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6396. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Sandoz Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6397. Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Sandoz Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

J. CAUSES OF ACTION AGAINST DEFENDANT STRIDES WITH RESPECT TO PRESCRIPTION RANITIDINE

5188. Plaintiffs identified in the table below bring claims against Defendant Strides with respect to prescription ranitidine on behalf of themselves and their respective State Strides Prescription Medical Monitoring Classes under the laws of their respective states of usage. Each

Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Kevin Nelson	DC
Ana Pereira	FL
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Jeannie Black	FL
Joyce Taylor	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Sonia Diaz	FL
Karen Foster	FL
Rebecca Sizemore	IN
Teresa Dowler	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Darlene Whittington-Coates	MD
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO

Plaintiff Name	State of Usage
Michael Galloway	OH
Patricia Hess	OH
Felicia Ball	PA
Joyce Guerrieri	PA
Teresa Waters	UT
Mynetta Hastings	WV

1. Arizona

COUNT 356:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

6398. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6399. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6400. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6401. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6402. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

6403. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6404. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6405. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6406. The latent injuries from which Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6407. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6408. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6409. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6410. Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6411. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Arizona Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6412. Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 357:
Negligent Product Containers – Arizona

6413. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6414. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6415. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6416. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6417. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6418. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6419. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6420. The latent injuries from which Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6421. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6422. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6423. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6424. Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6425. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6426. Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 358:
Negligent Storage and Transportation – Arizona

6427. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6428. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6429. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6430. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6431. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6432. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6433. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Arizona Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6434. The latent injuries from which Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6435. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6436. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6437. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6438. Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6439. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6440. Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 359:
Negligence – Failure to Warn Through Proper Expiration Dates – California

6441. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6442. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, Virginia Aragon, individually and on behalf of the California Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6443. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6444. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6445. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

6446. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6447. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6448. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6449. The latent injuries from which Plaintiffs and the California Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6450. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6451. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6452. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6453. Plaintiffs and the California Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6454. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6455. Plaintiffs and the California Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 360:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

6456. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6457. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6458. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6459. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6460. Under California law, manufacturers (including Defendant) bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes

"a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

6461. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

6462. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6463. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

6464. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

6465. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6466. The latent injuries from which Plaintiffs and the California Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6467. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6468. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6469. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6470. Plaintiffs and the California Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6471. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6472. Plaintiffs and the California Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 361:
Negligent Product Containers – California

6473. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

6474. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6475. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6476. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6477. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6478. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6479. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6480. The latent injuries from which Plaintiffs and the California Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6481. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6482. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6483. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6484. Plaintiffs and the California Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6485. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all California Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6486. Plaintiffs and the California Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 362:
Negligent Storage and Transportation – California

6487. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6488. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6489. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6490. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6491. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6492. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6493. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and California Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6494. The latent injuries from which Plaintiffs and the California Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6495. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6496. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6497. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6498. Plaintiffs and the California Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6499. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6500. Plaintiffs and the California Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. District of Columbia

COUNT 363:
Negligence – Failure to Warn Through Proper Expiration Dates – District of Columbia

6501. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6502. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6503. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6504. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6505. Under District of Columbia law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

6506. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6507. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6508. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6509. The latent injuries from which Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject

Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6510. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6511. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6512. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6513. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6514. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all District of Columbia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6515. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 364:
Negligence – Failure to Warn Consumers Through the FDA – District of Columbia

6516. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6517. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6518. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6519. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6520. Under District of Columbia law, there exists a duty owed by Defendant under failure to warn and negligence principles to follow FDA reporting requirements and notify the FDA of new information. *See Kubicki ex rel. Kubicki v. Medtronic*, No. CIV.A. 12-00734 CKK, 2013 WL 1739580, at *6–*8 (D.D.C. Mar. 21, 2013) ("[T]he Complaint alleges that Defendants knew, or should have known that technical problems were occurring in the 522 Pump subsequent to PMA approval, but never notified the FDA … despite their obligations under the federal regulations to do so. … Relatedly, the Complaint alleges failure to conduct post-approval market surveillance, including reporting all serious adverse events …. Accordingly, Plaintiffs have sufficiently pled parallel claims….") (citing, *inter alia*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232–33 (9th Cir. 2013)).

6521. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

6522. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6523. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

6524. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached Defendant's duty of reasonable care.

6525. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and District of Columbia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6526. The latent injuries from which Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6527. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6528. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6529. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6530. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6531. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6532. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them

for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 365:
Negligent Product Containers – District of Columbia

6533. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6534. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6535. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6536. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6537. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6538. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6539. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and District of Columbia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6540. The latent injuries from which Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6541. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6542. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6543. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6544. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6545. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6546. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 366:
Negligent Storage and Transportation – District of Columbia

6547. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6548. This cause of action is brought by Kevin Nelson, individually and on behalf of the District of Columbia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6549. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6550. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6551. Under District of Columbia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6552. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6553. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and District of Columbia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6554. The latent injuries from which Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6555. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6556. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6557. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6558. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6559. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all District of Columbia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6560. Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the District of Columbia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 367:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

6561. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6562. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6563. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6564. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6565. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6566. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light

of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

6567. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6568. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6569. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6570. The latent injuries from which Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6571. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6572. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6573. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6574. Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6575. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6576. Plaintiffs and the Florida Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 368:
Medical Monitoring – Negligent Product Containers – Florida

6577. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6578. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6579. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6580. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6581. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6582. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6583. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6584. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6585. The latent injuries from which Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6586. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6587. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6588. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6589. Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6590. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6591. Plaintiffs and the Florida Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 369:
Medical Monitoring – Negligent Storage and Transportation – Florida

6592. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6593. This cause of action is brought by Ana Pereira, Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Jeannie Black, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Tomlinson, Sonia Diaz, and Karen Foster, individually and on behalf of the Florida Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6594. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6595. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6596. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6597. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6598. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6599. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Florida Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6600. The latent injuries from which Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6601. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6602. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6603. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6604. Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6605. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6606. Plaintiffs and the Florida Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 370:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

6607. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6608. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6609. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6610. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6611. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

6612. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6613. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6614. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6615. The latent injuries from which Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6616. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6617. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6618. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6619. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6620. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6621. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 371:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

6622. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6623. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6624. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6625. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6626. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

6627. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

6628. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6629. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6630. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that

were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

6631. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6632. The latent injuries from which Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6633. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6634. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6635. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6636. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6637. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6638. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 372:
Negligent Product Containers – Indiana

6639. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6640. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6641. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6642. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6643. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6644. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6645. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6646. The latent injuries from which Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6647. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6648. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6649. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6650. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6651. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6652. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 373:
Negligent Storage and Transportation – Indiana

6653. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6654. This cause of action is brought by Rebecca Sizemore, Teresa Dowler, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6655. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6656. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6657. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6658. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6659. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Indiana Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6660. The latent injuries from which Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6661. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6662. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6663. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6664. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6665. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6666. Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 374:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

6667. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6668. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6669. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6670. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6671. Under Maryland law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

6672. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6673. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6674. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6675. The latent injuries from which Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6676. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6677. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6678. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6679. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6680. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Maryland Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6681. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 375:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

6682. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6683. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6684. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6685. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6686. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

6687. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

6688. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6689. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather

than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6690. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

6691. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6692. The latent injuries from which Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6693. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6694. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6695. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6696. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6697. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6698. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 376:
Negligent Product Containers – Maryland

6699. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6700. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6701. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6702. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6703. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6704. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6705. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6706. The latent injuries from which Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6707. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6708. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6709. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6710. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6711. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6712. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 377:
Negligent Storage and Transportation – Maryland

6713. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6714. This cause of action is brought by Alberta Griffin and Darlene Whittington-Coates, individually and on behalf of the Maryland Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6715. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6716. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6717. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6718. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6719. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Maryland Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have

suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6720. The latent injuries from which Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6721. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6722. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6723. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6724. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6725. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6726. Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 378:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

6727. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6728. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6729. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6730. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6731. Under Missouri law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

6732. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6733. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6734. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6735. The latent injuries from which Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6736. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6737. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6738. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6739. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay

for the medical monitoring and diagnosis of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6740. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6741. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 379:
Strict Products Liability – Failure to Warn Consumers Through the FDA – Missouri

6742. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

6743. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6744. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6745. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

6746. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

6747. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6748. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather

than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6749. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

6750. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6751. The latent injuries from which Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6752. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6753. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6754. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6755. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6756. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6757. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 380:
Negligent Product Containers – Missouri

6758. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6759. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6760. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6761. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6762. Under Missouri law, a manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6763. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6764. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6765. The latent injuries from which Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6766. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6767. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6768. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6769. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6770. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6771. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 381:
Negligent Storage and Transportation – Missouri

6772. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6773. This cause of action is brought by Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6774. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6775. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6776. Under Missouri law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6777. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6778. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Missouri Strides Prescription Medical Monitoring Class members have sustained a

significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6779. The latent injuries from which Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6780. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6781. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6782. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6783. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay

for the medical monitoring and diagnosis of Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6784. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6785. Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Ohio

COUNT 382:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

6786. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6787. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6788. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6789. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6790. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

6791. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6792. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6793. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Strides Prescription

Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6794. The latent injuries from which Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6795. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6796. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6797. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6798. Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6799. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6800. Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 383:
Negligent Product Containers – Ohio

6801. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

6802. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6803. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6804. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6805. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6806. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6807. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6808. The latent injuries from which Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6809. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6810. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6811. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6812. Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6813. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6814. Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 384:
Negligent Storage and Transportation – Ohio

6815. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6816. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6817. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6818. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6819. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6820. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6821. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Ohio Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6822. The latent injuries from which Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6823. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6824. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6825. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6826. Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6827. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6828. Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Pennsylvania

COUNT 385:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Pennsylvania

6829. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6830. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6831. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6832. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6833. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6834. Under Pennsylvania law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning.

6835. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6836. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6837. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6838. The latent injuries from which Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6839. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6840. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6841. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6842. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6843. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6844. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 386:
Medical Monitoring – Failure to Warn Consumers Through the FDA – Pennsylvania

6845. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6846. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6847. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6848. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

6849. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6850. Pennsylvania law "may impose liability for the failure to report to the FDA. …the duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

6851. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

6852. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

6853. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

6854. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

6855. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6856. The latent injuries from which Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6857. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6858. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6859. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6860. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6861. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6862. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 387:
Medical Monitoring – Negligent Product Containers – Pennsylvania

6863. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6864. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6865. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6866. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6867. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6868. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6869. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6870. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Pennsylvania Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6871. The latent injuries from which Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6872. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6873. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6874. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6875. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6876. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6877. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 388:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

6878. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6879. This cause of action is brought by Elmer Cook, Felicia Ball, and Joyce Guerrieri, individually and on behalf of the Pennsylvania Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6880. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6881. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6882. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6883. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6884. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6885. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Pennsylvania Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6886. The latent injuries from which Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6887. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6888. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6889. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6890. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6891. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6892. Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Pennsylvania Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. Utah

COUNT 389:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Utah

6893. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6894. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6895. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6896. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) Defendant.

6897. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6898. Under Utah law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the dangers from a foreseeable use of its product that it knows or should have known about.

6899. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6900. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6901. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Utah Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6902. The latent injuries from which Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6903. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6904. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6905. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6906. Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6907. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6908. Plaintiffs and the Utah Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 390:
Medical Monitoring – Negligent Product Containers – Utah

6909. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6910. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6911. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6912. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6913. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6914. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6915. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6916. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Utah Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6917. The latent injuries from which Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6918. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6919. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6920. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6921. Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6922. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6923. Plaintiffs and the Utah Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 391:
Medical Monitoring – Negligent Storage and Transportation – Utah

6924. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6925. This cause of action is brought by Teresa Waters, individually and on behalf of the Utah Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6926. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6927. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6928. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6929. Under Utah law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6930. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6931. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Utah Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6932. The latent injuries from which Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6933. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6934. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6935. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6936. Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6937. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Utah Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6938. Plaintiffs and the Utah Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Utah Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. West Virginia

COUNT 392:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

6939. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6940. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6941. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6942. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6943. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6944. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

6945. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6946. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6947. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6948. The latent injuries from which Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6949. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6950. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6951. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6952. Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6953. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6954. Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 393:
Medical Monitoring – Negligent Product Containers – West Virginia

6955. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6956. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6957. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6958. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

6959. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6960. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

6961. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

6962. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6963. The latent injuries from which Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6964. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6965. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6966. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6967. Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6968. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6969. Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 394:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

6970. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6971. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

6972. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6973. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

6974. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

6975. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

6976. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

6977. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic

Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and West Virginia Strides Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6978. The latent injuries from which Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6979. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6980. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6981. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6982. Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program

which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6983. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

6984. Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

K. CAUSES OF ACTION AGAINST DEFENDANT TEVA WITH RESPECT TO PRESCRIPTION RANITIDINE

6985. Plaintiffs identified in the table below bring claims against Defendant Teva with respect to prescription ranitidine on behalf of themselves and their respective State Teva Prescription Medical Monitoring Classes under the laws of their respective states of usage. Each

Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Armando Tapia	AZ
Golbenaz Bakhtiar	CA
Royal Handy	CA
Virginia Aragon	CA
Jeffrey Pisano	CO
Clifton McKinnon	FL
Daniel Taylor	FL
Hattie Kelley	FL
Irma Arcaya	FL
Joyce Taylor	FL
Alexander Monger	FL
Laura Monger	FL
Marva Mccall	FL
Michael Fesser	FL
Michael Tomlinson	FL
Karen Foster	FL
Rebecca Sizemore	IN
Tracy Wells	IN
Timberly Goble	IN
Alberta Griffin	MD
Antrenise Campbell	MO
Brenda Newcomb	MO
Cynthia Gibbs	MO
Elaine Aaron	MO
Michael Galloway	OH; FL
Patricia Hess	OH

Plaintiff Name	State of Usage
Felicia Ball	PA
Joyce Guerrieri	PA
Mynetta Hastings	WV

1. Arizona

COUNT 395:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

6986. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

6987. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

6988. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

6989. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

6990. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

6991. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

6992. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

6993. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6994. The latent injuries from which Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

6995. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

6996. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

6997. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

6998. Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

6999. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7000. Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 396:
Negligent Product Containers – Arizona

7001. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7002. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7003. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7004. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to Defendant.

7005. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7006. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7007. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Arizona Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7008. The latent injuries from which Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7009. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7010. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7011. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7012. Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7013. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7014. Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 397:
Negligent Storage and Transportation – Arizona

7015. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7016. This cause of action is brought by Armando Tapia, individually and on behalf of the Arizona Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7017. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7018. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7019. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7020. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7021. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer

Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Arizona Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7022. The latent injuries from which Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7023. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7024. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7025. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7026. Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7027. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7028. Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 398:
Negligence – Failure to Warn Through Proper Expiration Dates – California

7029. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7030. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7031. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7032. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7033. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

7034. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7035. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7036. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7037. The latent injuries from which Plaintiffs and the California Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7038. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7039. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7040. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7041. Plaintiffs and the California Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the California Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7042. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7043. Plaintiffs and the California Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 399:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

7044. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7045. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7046. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7047. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

7048. Under California law, manufacturers (including Defendant) bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

7049. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

7050. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

7051. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

7052. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

7053. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7054. The latent injuries from which Plaintiffs and the California Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7055. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7056. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7057. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7058. Plaintiffs and the California Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7059. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7060. Plaintiffs and the California Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 400:
Negligent Product Containers – California

7061. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7062. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7063. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7064. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7065. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7066. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7067. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and California Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7068. The latent injuries from which Plaintiffs and the California Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7069. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7070. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7071. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7072. Plaintiffs and the California Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7073. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7074. Plaintiffs and the California Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 401:
Negligent Storage and Transportation – California

7075. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7076. This cause of action is brought by Golbenaz Bakhtiar, Royal Handy, and Virginia Aragon, individually and on behalf of the California Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7077. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7078. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7079. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7080. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7081. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and California Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7082. The latent injuries from which Plaintiffs and the California Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7083. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7084. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7085. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7086. Plaintiffs and the California Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7087. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7088. Plaintiffs and the California Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 402:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

7089. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7090. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7091. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7092. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7093. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7094. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

7095. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7096. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7097. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Colorado Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7098. The latent injuries from which Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7099. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7100. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7101. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7102. Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7103. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7104. Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 403:
Medical Monitoring – Negligent Product Containers – Colorado

7105. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7106. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7107. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7108. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7109. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7110. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7111. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7112. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Colorado Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7113. The latent injuries from which Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7114. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7115. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7116. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7117. Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7118. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7119. Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 404:
Medical Monitoring – Negligent Storage and Transportation – Colorado

7120. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7121. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7122. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7123. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7124. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7125. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7126. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7127. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Colorado Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7128. The latent injuries from which Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7129. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7130. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7131. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7132. Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7133. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7134. Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 405:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

7135. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7136. This cause of action is brought by Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Joyce Taylor, Alexander Monger, Laura Monger, Marva Mccall, Michael Fesser, Michael Galloway, Michael Tomlinson, and Karen Foster, individually and on behalf of the Florida Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7137. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7138. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7139. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7140. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7141. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7142. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7143. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7144. The latent injuries from which Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7145. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7146. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7147. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7148. Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7149. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7150. Plaintiffs and the Florida Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 406:
Medical Monitoring – Negligent Product Containers – Florida

7151. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7152. This cause of action is brought by Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Joyce Taylor, Marva Mccall, Michael Fesser, Michael Galloway, Michael Tomlinson, and Karen Foster, individually and on behalf of the Florida Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7153. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7154. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7155. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7156. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7157. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7158. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Florida Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7159. The latent injuries from which Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7160. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7161. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7162. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7163. Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7164. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7165. Plaintiffs and the Florida Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 407:
Medical Monitoring – Negligent Storage and Transportation – Florida

7166. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7167. This cause of action is brought by Clifton McKinnon, Daniel Taylor, Hattie Kelley, Irma Arcaya, Joyce Taylor, Alexander Monger, Laura Monger, Marva Mccall, Michael Fesser, Michael Galloway, Michael Tomlinson, and Karen Foster, individually and on behalf of the Florida Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7168. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7169. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7170. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7171. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7172. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7173. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Florida Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7174. The latent injuries from which Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7175. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7176. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7177. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7178. Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7179. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7180. Plaintiffs and the Florida Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Indiana

COUNT 408:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

7181. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7182. This cause of action is brought by Rebecca Sizemore, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7183. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7184. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7185. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

7186. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7187. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7188. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7189. The latent injuries from which Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7190. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7191. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7192. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7193. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7194. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7195. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 409:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

7196. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7197. This cause of action is brought by Rebecca Sizemore, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7198. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7199. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

7200. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

7201. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

7202. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

7203. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

7204. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that

were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

7205. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7206. The latent injuries from which Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7207. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7208. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7209. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7210. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7211. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7212. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 410:
Negligent Product Containers – Indiana

7213. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7214. This cause of action is brought by Rebecca Sizemore, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7215. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7216. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7217. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7218. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7219. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Indiana Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7220. The latent injuries from which Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7221. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7222. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7223. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7224. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7225. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7226. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 411:
Negligent Storage and Transportation – Indiana

7227. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7228. This cause of action is brought by Rebecca Sizemore, Tracy Wells, and Timberly Goble, individually and on behalf of the Indiana Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7229. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7230. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7231. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7232. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7233. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Indiana Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7234. The latent injuries from which Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7235. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7236. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7237. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7238. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7239. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7240. Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Maryland

COUNT 412:
Negligence – Failure to Warn Through Proper Expiration Dates – Maryland

7241. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7242. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7243. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7244. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7245. Under Maryland law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

7246. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7247. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7248. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7249. The latent injuries from which Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7250. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7251. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7252. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7253. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7254. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Maryland Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7255. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 413:
Negligence – Failure to Warn Consumers Through the FDA – Maryland

7256. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7257. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7258. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7259. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

7260. Under Maryland law, a "failure to warn claim is parallel. Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in ... a product liability action....' *Gourdine v. Crews*, 405 Md. 722, 955 A.2d 769, 779 (2008). Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. *Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 646 (1992). And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015).

7261. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

7262. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

7263. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather

than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

7264. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of to make reasonable efforts to ensure an effective warning reached consumers.

7265. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7266. The latent injuries from which Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7267. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7268. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7269. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7270. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7271. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7272. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 414:
Negligent Product Containers – Maryland

7273. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7274. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7275. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7276. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7277. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7278. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7279. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Maryland Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7280. The latent injuries from which Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7281. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7282. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7283. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7284. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7285. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7286. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 415:
Negligent Storage and Transportation – Maryland

7287. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7288. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7289. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7290. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7291. Under Maryland law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7292. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7293. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Maryland Teva Prescription Medical Monitoring Class members have sustained a significantly

increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7294. The latent injuries from which Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7295. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7296. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7297. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7298. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7299. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7300. Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Missouri

COUNT 416:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

7301. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription

Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7302. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7303. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7304. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7305. Under Missouri law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

7306. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7307. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7308. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing

serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7309. The latent injuries from which Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7310. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7311. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7312. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7313. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7314. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7315. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 417:
Strict Products Liability – Failure to Warn Consumers Through the FDA – Missouri

7316. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury),

as if fully stated herein.

7317. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7318. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7319. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

7320. Missouri imposes a duty to warn the FDA under "a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. … [This duty] is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements …." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017).

7321. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

7322. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

7323. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

7324. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Manufacturer Defendants also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

7325. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Missouri Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7326. The latent injuries from which Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7327. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7328. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7329. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7330. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7331. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7332. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 418:
Negligent Product Containers – Missouri

7333. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7334. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7335. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7336. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7337. Under Missouri law, a manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7338. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7339. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Missouri Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7340. The latent injuries from which Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7341. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7342. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7343. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7344. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7345. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7346. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 419:
Negligent Storage and Transportation – Missouri

7347. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7348. This cause of action is brought by Antrenise Campbell, Brenda Newcomb, Cynthia Gibbs, and Elaine Aaron, individually and on behalf of the Missouri Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7349. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7350. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7351. Under Missouri law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7352. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7353. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Missouri Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7354. The latent injuries from which Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7355. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7356. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7357. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7358. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7359. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7360. Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Ohio

COUNT 420:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

7361. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7362. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7363. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7364. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7365. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

7366. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7367. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7368. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7369. The latent injuries from which Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7370. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7371. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7372. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7373. Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7374. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7375. Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 421:
Negligent Product Containers – Ohio

7376. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7377. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7378. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7379. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7380. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7381. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7382. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Ohio Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7383. The latent injuries from which Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7384. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7385. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7386. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7387. Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7388. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7389. Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 422:
Negligent Storage and Transportation – Ohio

7390. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7391. This cause of action is brought by Michael Galloway and Patricia Hess, individually and on behalf of the Ohio Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7392. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7393. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7394. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7395. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7396. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Ohio Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7397. The latent injuries from which Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7398. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7399. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7400. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7401. Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7402. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7403. Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

9. Pennsylvania

COUNT 423:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Pennsylvania

7404. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7405. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7406. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7407. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7408. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7409. Under Pennsylvania law, a manufacturer, including Defendant, has a duty of reasonable care to provide an adequate warning.

7410. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7411. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7412. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7413. The latent injuries from which Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7414. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7415. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7416. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7417. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7418. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7419. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 424:
Medical Monitoring – Failure to Warn Consumers Through the FDA – Pennsylvania

7420. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7421. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7422. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7423. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

7424. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7425. Pennsylvania law "may impose liability for the failure to report to the FDA. …the duty to warn is discharged by 'providing information about the product's dangerous propensities,' which undoubtedly encompasses Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) ("we follow the reasoning of the en banc decision in *Stengel*"); *Bull v. St. Jude Med., Inc.*, No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead based on the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.").

7426. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning the FDA would be effective in warning the end consumer or her doctor, manufacturers have a state law duty to do so.

7427. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

7428. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

7429. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

7430. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Pennsylvania Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7431. The latent injuries from which Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7432. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7433. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7434. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7435. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7436. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7437. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 425:
Medical Monitoring – Negligent Product Containers – Pennsylvania

7438. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7439. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7440. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7441. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to Defendant.

7442. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7443. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7444. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7445. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and Pennsylvania Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7446. The latent injuries from which Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7447. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7448. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7449. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7450. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7451. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7452. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 426:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

7453. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7454. This cause of action is brought by Felicia Ball and Joyce Guerrieri, individually and on behalf of the Pennsylvania Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7455. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7456. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7457. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7458. Under Pennsylvania law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7459. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7460. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and Pennsylvania Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7461. The latent injuries from which Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7462. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7463. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7464. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7465. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7466. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7467. Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Pennsylvania Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

10. West Virginia

COUNT 427:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

7468. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7469. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7470. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7471. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

7472. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7473. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

7474. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7475. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7476. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7477. The latent injuries from which Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7478. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7479. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7480. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7481. Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7482. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7483. Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products.

Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 428:
Medical Monitoring – Negligent Product Containers – West Virginia

7484. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7485. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7486. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7487. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

7488. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7489. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

7490. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7491. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and therefore Plaintiffs and West Virginia Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7492. The latent injuries from which Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7493. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7494. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7495. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7496. Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7497. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7498. Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 429:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

7499. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 428-50 (describing Generic Prescription Manufacturers' failure to warn), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7500. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Teva Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Teva (for the purposes of this Count, "Defendant").

7501. The allegations in this Count apply to Teva during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7502. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

7503. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7504. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

7505. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

7506. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and West Virginia Teva Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7507. The latent injuries from which Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7508. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7509. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7510. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7511. Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

7512. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Teva Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7513. Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Teva Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

L. CAUSES OF ACTION AGAINST DEFENDANT CVS WITH RESPECT TO CVS HEALTH-BRANDED RANITIDINE

7514. Plaintiffs identified in the table below bring claims against Defendant CVS with respect to CVS Health-branded OTC ranitidine on behalf of themselves and their respective State CVS Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations

set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1. California

Count 430:
Negligence – Failure to Warn Through Proper Expiration Dates – California

7515. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7516. This cause of action is brought by Richard Obrien, individually and on behalf of the California CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7517. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7518. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to CVS.

7519. Under California law, Defendant had a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7520. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7521. Plaintiffs have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7522. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7523. The latent injuries from which Plaintiffs and the California CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7524. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7525. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7526. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7527. Plaintiffs and the California CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7528. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7529. Plaintiffs and the California CVS Medical Monitoring Class have an inadequate

remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 431:
Negligent Product Containers – California

7530. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7531. This cause of action is brought by Richard Obrien, individually and on behalf of the California CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7532. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7533. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to CVS.

7534. Under California law, Defendant had a duty to exercise reasonable care in choosing and making the containers for its products.

7535. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7536. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and California CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7537. The latent injuries from which Plaintiffs and the California CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7538. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7539. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7540. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California CVS

Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7541. Plaintiffs and the California CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7542. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7543. Plaintiffs and the California CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 432:
Negligent Storage and Transportation – California

7544. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91

(describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7545. This cause of action is brought by Richard Obrien, individually and on behalf of the California CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7546. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7547. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to CVS.

7548. Under California law, Defendant had a duty to exercise reasonable care in transporting and storing products.

7549. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7550. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and California CVS Medical Monitoring Class members have sustained a significantly increased risk

of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7551. The latent injuries from which Plaintiffs and the California CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7552. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7553. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7554. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7555. Plaintiffs and the California CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California CVS Medical Monitoring Class members as

frequently and appropriately as necessary.

7556. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7557. Plaintiffs and the California CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Indiana

COUNT 433:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

7558. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7559. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7560. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7561. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to CVS.

7562. Under Indiana law, Defendant has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

7563. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7564. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7565. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Indiana CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7566. The latent injuries from which Plaintiffs and the Indiana CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7567. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7568. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7569. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7570. Plaintiffs and the Indiana CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7571. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7572. Plaintiffs and the Indiana CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 434:
Negligent Product Containers – Indiana

7573. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7574. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7575. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7576. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to CVS.

7577. Under Indiana law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

7578. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7579. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Indiana CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7580. The latent injuries from which Plaintiffs and the Indiana CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7581. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7582. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7583. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7584. Plaintiffs and the Indiana CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7585. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7586. Plaintiffs and the Indiana CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-

approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 435:
Negligent Storage and Transportation – Indiana

7587. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7588. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7589. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7590. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to CVS.

7591. Under Indiana law, Defendant had a duty to exercise reasonable care in transporting and storing products.

7592. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7593. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Indiana CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7594. The latent injuries from which Plaintiffs and the Indiana CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7595. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7596. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7597. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without

adequate treatment will be significantly reduced.

7598. Plaintiffs and the Indiana CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7599. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7600. Plaintiffs and the Indiana CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Ohio

COUNT 436:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

7601. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91

(describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7602. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7603. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7604. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to CVS.

7605. Under Ohio law, Defendant has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

7606. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on its Ranitidine-Containing Products were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7607. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and Ohio CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7608. The latent injuries from which Plaintiffs and the Ohio CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7609. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7610. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7611. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7612. Plaintiffs and the Ohio CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio CVS Medical Monitoring Class members for the Subject

Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7613. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7614. Plaintiffs and the Ohio CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 437:
Negligent Product Containers – Ohio

7615. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and

975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7616. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7617. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7618. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to CVS.

7619. Under Ohio law, Defendant had a duty to exercise reasonable care in choosing and making the containers for its products.

7620. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7621. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Ohio CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7622. The latent injuries from which Plaintiffs and the Ohio CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting

Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7623. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7624. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7625. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7626. Plaintiffs and the Ohio CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7627. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio CVS Medical Monitoring Class members in writing that they may require

frequent medical monitoring for the purpose of diagnosis.

7628. Plaintiffs and the Ohio CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 438:
Negligent Storage and Transportation – Ohio

7629. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7630. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7631. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7632. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to CVS.

7633. Under Ohio law, Defendant has a duty to exercise reasonable care in transporting and storing products.

7634. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7635. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, Plaintiffs and Ohio CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7636. The latent injuries from which Plaintiffs and the Ohio CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7637. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7638. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7639. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7640. Plaintiffs and the Ohio CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7641. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7642. Plaintiffs and the Ohio CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. West Virginia

COUNT 439:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

7643. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7644. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7645. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7646. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to CVS.

7647. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7648. Under West Virginia law, Defendant has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably

dangerous if distributed without a particular warning.

7649. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7650. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7651. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7652. The latent injuries from which Plaintiffs and the West Virginia CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7653. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7654. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7655. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7656. Plaintiffs and the West Virginia CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7657. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7658. Plaintiffs and the West Virginia CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia CVS Medical Monitoring Class members will continue to face an

unreasonable risk of injury and disability and remain undiagnosed.

COUNT 440:
Medical Monitoring – Negligent Product Containers – West Virginia

7659. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7660. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7661. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7662. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to CVS.

7663. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

7664. Under West Virginia law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

7665. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7666. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and West Virginia CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7667. The latent injuries from which Plaintiffs and the West Virginia CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7668. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7669. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7670. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7671. Plaintiffs and the West Virginia CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7672. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7673. Plaintiffs and the West Virginia CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 441:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

7674. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after

ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 451-55 (describing Store-Brand Defendants' failure to warn), 456-506 (describing CVS-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7675. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia CVS Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against CVS (for the purposes of this Count, "Defendant").

7676. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling CVS Health-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7677. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to CVS.

7678. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

7679. Under West Virginia law, Defendant has a duty to exercise reasonable care in transporting and storing products.

7680. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7681. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and West Virginia CVS Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

7682. The latent injuries from which Plaintiffs and the West Virginia CVS Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7683. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7684. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7685. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia CVS Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7686. Plaintiffs and the West Virginia CVS Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia CVS Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia CVS Medical Monitoring Class members as frequently and appropriately as necessary.

7687. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia CVS Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7688. Plaintiffs and the West Virginia CVS Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia CVS Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

M. CAUSES OF ACTION AGAINST DEFENDANT RITE AID WITH RESPECT TO RITE AID-BRANDED RANITIDINE

7689. Plaintiffs identified in the table below bring claims against Defendant CVS with respect to Rite Aid-branded OTC ranitidine on behalf of themselves and their respective State Rite Aid Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

COUNT 442:
Negligence – Failure to Warn Through Proper Expiration Dates – California

7690. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 507-43 (describing Rite Aid-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7691. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Rite Aid (for the purposes of this Count, "Defendant").

7692. The allegations in this Count apply to Rite Aid during the time period in which it was manufacturing, shipping, storing, handling, and/or selling its Rite Aid-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated by reference.

7693. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Rite Aid.

7694. Under California law, Defendant had a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7695. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7696. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7697. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7698. The latent injuries from which Plaintiffs and the California Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7699. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7700. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7701. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7702. Plaintiffs and the California Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

7703. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7704. Plaintiffs and the California Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 443:
Negligent Product Containers – California

7705. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 507-43 (describing Rite Aid-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7706. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Rite Aid (for the purposes of this Count, "Defendant").

7707. The allegations in this Count apply to Rite Aid during the time period in which it was manufacturing, shipping, storing, handling, and/or selling its Rite Aid-branded Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

7708. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Rite Aid.

7709. Under California law, Defendant had a duty to exercise reasonable care in choosing and making the containers for its products.

7710. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7711. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and California Rite Aid

Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7712. The latent injuries from which Plaintiff and the California Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7713. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7714. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7715. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7716. Plaintiffs and the California Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the California Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

7717. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7718. Plaintiffs and the California Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 444:
Negligent Storage and Transportation – California

7719. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 507-43 (describing Rite Aid-specific allegations), and 975-85 (describing

Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7720. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Rite Aid (for the purposes of this Count, "Defendant").

7721. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Rite Aid-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7722. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Rite Aid.

7723. Under California law, Defendant had a duty to exercise reasonable care in transporting and storing products.

7724. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7725. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiff and California Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7726. The latent injuries from which Plaintiff and the California Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7727. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7728. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7729. By monitoring and testing Plaintiffs, the risk that Plaintiff and the California Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7730. Plaintiff and the California Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the California Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the California Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

7731. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Rite Aid Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

7732. Plaintiff and the California Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the California Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

N. CAUSES OF ACTION AGAINST DEFENDANT WALGREENS WITH RESPECT TO WAL-ZAN-BRANDED RANITIDINE

7733. Plaintiffs identified in the table below bring claims against Defendant CVS with respect to Wal-Zan-branded OTC ranitidine on behalf of themselves and their respective State Walgreens Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiffs incorporates by reference the allegations specific to them from Section III.B. and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1. Arizona

COUNT 445:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

7734. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91

(describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7735. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7736. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7737. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walgreens.

7738. Under Arizona law, Defendant has a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7739. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7740. Plaintiffs or their doctors would have read and heeded these warnings had they been

included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7741. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7742. The latent injuries from which Plaintiffs and the Arizona Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7743. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7744. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7745. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

7746. Plaintiffs and the Arizona Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7747. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7748. Plaintiffs and the Arizona Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 446:
Negligent Product Containers – Arizona

7749. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics),

185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7750. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7751. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

7752. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walgreens.

7753. Under Arizona law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

7754. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7755. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Arizona Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses

and expenses associated with ongoing medical monitoring.

7756. The latent injuries from which Plaintiffs and the Arizona Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7757. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7758. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7759. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7760. Plaintiffs and the Arizona Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7761. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7762. Plaintiffs and the Arizona Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 447:
Negligent Storage and Transportation – Arizona

7763. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7764. This cause of action is brought by Tangie Sims, individually and on behalf of the

Arizona Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7765. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7766. Plaintiffs also incorporates herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walgreens.

7767. Under Arizona law, Defendant has a duty to exercise reasonable care in transporting and storing products.

7768. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7769. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Arizona Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7770. The latent injuries from which Plaintiffs and the Arizona Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7771. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7772. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7773. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7774. Plaintiffs and the Arizona Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7775. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7776. Plaintiffs and the Arizona Walgreens Medical Monitoring Class have an inadequate

remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 448:
Negligence – Failure to Warn Through Proper Expiration Dates – California

7777. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7778. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7779. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7780. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-

Specific Allegations) as to Walgreens.

7781. Under California law, Defendant has a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7782. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7783. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7784. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7785. The latent injuries from which Plaintiffs and the California Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7786. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7787. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7788. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7789. Plaintiffs and the California Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7790. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7791. Plaintiffs and the California Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 449:
Negligent Product Containers – California

7792. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7793. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7794. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7795. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walgreens.

7796. Under California law, Defendant had a duty to exercise reasonable care in choosing

and making the containers for its products.

7797. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7798. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and California Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7799. The latent injuries from which Plaintiffs and the California Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7800. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7801. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7802. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses

without adequate treatment will be significantly reduced.

7803. Plaintiffs and the California Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7804. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7805. Plaintiffs and the California Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 450:
Negligent Storage and Transportation – California

7806. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics),

185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7807. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7808. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7809. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walgreens.

7810. Under California law, Defendant had a duty to exercise reasonable care in transporting and storing products.

7811. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7812. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and California Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

7813. The latent injuries from which Plaintiffs and the California Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7814. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7815. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7816. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7817. Plaintiffs and the California Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7818. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7819. Plaintiffs and the California Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffsand the California Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 451:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

7820. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7821. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7822. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7823. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walgreens.

7824. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

7825. Under Colorado law, Defendant has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

7826. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7827. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7828. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Colorado Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing

serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7829. The latent injuries from which Plaintiffs and the Colorado Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7830. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7831. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7832. By monitoring and testing Plaintiffs, the risk that Plaintiffs sand the Colorado Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7833. Plaintiffs and the Colorado Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Walgreens Medical

Monitoring Class members as frequently and appropriately as necessary.

7834. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7835. Plaintiffs and the Colorado Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 452:
Medical Monitoring – Negligent Product Containers – Colorado

7836. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7837. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7838. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7839. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walgreens.

7840. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers

7841. Under Colorado law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

7842. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7843. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Colorado Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7844. The latent injuries from which Plaintiffs and the Colorado Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7845. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7846. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7847. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7848. Plaintiffs and the Colorado Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7849. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Walgreens Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

7850. Plaintiffs and the Colorado Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 453:
Medical Monitoring – Negligent Storage and Transportation – Colorado

7851. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7852. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7853. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7854. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walgreens.

7855. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

7856. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

7857. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7858. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7859. The latent injuries from which Plaintiffs and the Colorado Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7860. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

7861. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7862. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7863. Plaintiffs and the Colorado Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7864. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7865. Plaintiffs and the Colorado Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Colorado Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 454:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

7866. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7867. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7868. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7869. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walgreens.

7870. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

7871. Under Florida law, Defendant has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7872. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7873. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7874. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7875. The latent injuries from which Plaintiffs and the Florida Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7876. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7877. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7878. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7879. Plaintiffs and the Florida Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7880. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7881. Plaintiffs and the Florida Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term

physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7882. Under Florida law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

7883. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7884. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

COUNT 455:
Medical Monitoring – Negligent Product Containers – Florida

7885. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants'

failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7886. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Walgreens Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7887. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7888. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walgreens.

7889. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

7890. Under Florida law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

7891. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7892. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Florida Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7893. The latent injuries from which Plaintiffs and the Florida Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7894. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7895. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7896. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7897. Plaintiffs and the Florida Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7898. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7899. Plaintiffs and the Florida Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 456:
Medical Monitoring – Storage and Transportation – Florida

7900. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 544-86 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7901. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walgreens (for the purposes of this Count, "Defendant").

7902. The allegations in this Count apply to Defendant during the time period in which it

was manufacturing, shipping, storing, handling, and/or selling Wal-Zan-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7903. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walgreens.

7904. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

7905. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

7906. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7907. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Florida Walgreens Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7908. The latent injuries from which Plaintiffs and the Florida Walgreens Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7909. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7910. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7911. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Walgreens Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7912. Plaintiffs and the Florida Walgreens Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Walgreens Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Walgreens Medical Monitoring Class members as frequently and appropriately as necessary.

7913. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Walgreens Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7914. Plaintiffs and the Florida Walgreens Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term

physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Walgreens Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

O. CAUSES OF ACTION AGAINST DEFENDANT WALMART WITH RESPECT TO EQUATE-BRANDED RANITIDINE

7915. Plaintiffs identified in the table below bring claims against Defendant Walmart with respect to Equate-branded ranitidine on behalf of themselves and their respective State Walmart Prescription Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

1. Arizona

COUNT 457:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

7916. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing

Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7917. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

7918. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7919. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walmart.

7920. Under Arizona law, Defendant has a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7921. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7922. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7923. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and Arizona Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7924. The latent injuries from which Plaintiffs and the Arizona Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7925. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7926. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7927. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7928. Plaintiffs and the Arizona Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Walmart Medical Monitoring Class members

for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

7929. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7930. Plaintiffs and the Arizona Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 458:
Negligent Product Containers – Arizona

7931. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants'

failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7932. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

7933. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7934. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walmart.

7935. Under Arizona law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

7936. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7937. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Arizona Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7938. The latent injuries from which Plaintiffs and the Arizona Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7939. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7940. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7941. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7942. Plaintiffs and the Arizona Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

7943. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Walmart Medical Monitoring Class members in writing that they may require

frequent medical monitoring for the purpose of diagnosis.

7944. Plaintiffs and the Arizona Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 459:
Negligent Storage and Transportation – Arizona

7945. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7946. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

7947. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7948. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walmart.

7949. Under Arizona law, Defendant has a duty to exercise reasonable care in transporting and storing products.

7950. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7951. As a direct and proximate result of these systemic, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Arizona Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7952. The latent injuries from which Plaintiffs and the Arizona Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7953. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7954. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7955. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7956. Plaintiffs and the Arizona Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

7957. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7958. Plaintiffs and the Arizona Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 460:
Negligence – Failure to Warn Through Proper Expiration Dates – California

7959. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7960. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

7961. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7962. Plaintiffs incorporate herein by reference paragraphs Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walmart.

7963. Under California law, Defendant has a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

7964. Defendant breached this duty for its Ranitidine-Containing Products. The

expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

7965. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

7966. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7967. The latent injuries from which Plaintiffs and the California Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7968. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7969. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

7970. By monitoring and testing Plaintiffs, the risk that Plaintiff and the California Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7971. Plaintiffs and the California Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

7972. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7973. Plaintiffs and the California Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 461:
Negligent Product Containers – California

7974. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7975. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

7976. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7977. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walmart.

7978. Under California law, Defendant had a duty to exercise reasonable care in choosing and making the containers for its products.

7979. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

7980. As a direct and proximate result of this failure, excessive levels of NDMA built up

in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and California Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7981. The latent injuries from which Plaintiffs and the California Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7982. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7983. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7984. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7985. Plaintiffs and the California Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Walmart Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

7986. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

7987. Plaintiffs and the California Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 462:
Negligent Storage and Transportation – California

7988. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants'

failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

7989. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

7990. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

7991. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walmart.

7992. Under California law, Defendant had a duty to exercise reasonable care in transporting and storing products.

7993. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

7994. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

7995. The latent injuries from which Plaintiffs and the California Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

7996. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

7997. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

7998. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

7999. Plaintiffs and the California Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8000. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all California Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8001. Plaintiffs and the California Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 463:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

8002. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8003. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8004. The allegations in this Count apply to Defendant during the time period in which it

was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8005. Plaintiffs incorporate herein by reference paragraphs Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walmart.

8006. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8007. Under Colorado law, Defendant has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

8008. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8009. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8010. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Colorado Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8011. The latent injuries from which Plaintiffs and the Colorado Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8012. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8013. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8014. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8015. Plaintiffs and the Colorado Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8016. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8017. Plaintiffs and the Colorado Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 464:
Medical Monitoring – Negligent Product Containers – Colorado

8018. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8019. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8020. The allegations in this Count apply to Defendant during the time period in which it

was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8021. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walmart.

8022. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8023. Under Colorado law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

8024. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8025. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Colorado Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8026. The latent injuries from which Plaintiffs and the Colorado Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8027. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8028. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8029. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8030. Plaintiffs and the Colorado Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8031. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8032. Plaintiffs and the Colorado Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-

approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 465:
Medical Monitoring – Negligent Storage and Transportation – Colorado

8033. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8034. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8035. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8036. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walmart.

8037. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8038. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

8039. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

8040. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Colorado Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8041. The latent injuries from which Plaintiffs and the Colorado Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8042. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8043. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8044. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8045. Plaintiffs and the Colorado Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8046. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8047. Plaintiffs and the Colorado Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 466:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

8048. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8049. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8050. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8051. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walmart.

8052. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8053. Under Florida law, Defendant has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of

manufacture and distribution.

8054. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8055. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8056. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8057. The latent injuries from which Plaintiffs and the Florida Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8058. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8059. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8060. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8061. Plaintiffs and the Florida Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8062. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8063. Plaintiffs and the Florida Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Walmart Medical Monitoring Class members will continue to face an unreasonable

risk of injury and disability and remain undiagnosed.

COUNT 467:
Medical Monitoring – Negligent Product Containers – Florida

8064. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8065. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8066. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8067. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walmart.

8068. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8069. Under Florida law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

8070. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8071. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Florida Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8072. The latent injuries from which Plaintiffs and the Florida Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8073. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8074. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8075. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8076. Plaintiffs and the Florida Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8077. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8078. Plaintiffs and the Florida Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 468:
Medical Monitoring – Negligent Storage and Transportation – Florida

8079. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after

ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8080. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8081. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8082. Plaintiffs also incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walmart.

8083. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8084. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

8085. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

8086. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and Florida Walmart Medical Monitoring Class members have sustained a significantly increased risk

of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8087. The latent injuries from which Plaintiffs and the Florida Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8088. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8089. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8090. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8091. Plaintiffs and the Florida Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Walmart Medical Monitoring Class

members as frequently and appropriately as necessary.

8092. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8093. Plaintiffs and the Florida Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. West Virginia

COUNT 469:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

8094. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing

Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8095. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8096. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

8097. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Walmart.

8098. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8099. Under West Virginia law, Defendant has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

8100. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8101. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8102. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of Ranitidine-Containing Products, Plaintiffs and West Virginia Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8103. The latent injuries from which Plaintiffs and the West Virginia Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8104. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8105. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8106. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8107. Plaintiffs and the West Virginia Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Walmart Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8108. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8109. Plaintiffs and the West Virginia Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 470:
Medical Monitoring – Negligent Product Containers – West Virginia

8110. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants'

failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8111. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8112. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference..

8113. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Walmart.

8114. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

8115. Under West Virginia law, Defendant has a duty to exercise reasonable care in choosing and making the containers for its products.

8116. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8117. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and West Virginia Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8118. The latent injuries from which Plaintiffs and the West Virginia Walmart Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8119. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8120. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8121. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8122. Plaintiffs and the West Virginia Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8123. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8124. Plaintiffs and the West Virginia Walmart Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 471:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

8125. Plaintiffs incorporate by reference each allegation set forth in paragraphs 78-91 (describing Store-Brand Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 451-55 (describing Store-Brand Defendants' failure to warn), 587-630 (describing Walgreens-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8126. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Walmart Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Walmart (for the purposes of this Count, "Defendant").

8127. The allegations in this Count apply to Defendant during the time period in which it was manufacturing, shipping, storing, handling, and/or selling Equate-branded Ranitidine-Containing Products, which is set forth in paragraphs 172-84 and incorporated herein by reference.

8128. Plaintiffs also incorporate herein by reference paragraphs Paragraphs 951-74 (Additional Count-Specific Allegations) as to Walmart.

8129. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8130. Under West Virginia law, Defendant has a duty to exercise reasonable care in transporting and storing products.

8131. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

8132. As a direct and proximate result of these systemic failures, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and West Virginia Walmart Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8133. The latent injuries from which Plaintiffs and the West Virginia Walmart Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8134. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8135. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8136. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Walmart Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8137. Plaintiffs and the West Virginia Walmart Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Walmart Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Walmart Medical Monitoring Class members as frequently and appropriately as necessary.

8138. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Walmart Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8139. Plaintiffs and the West Virginia Walmart Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Walmart Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

P. CAUSES OF ACTION AGAINST DEFENDANT APOTEX WITH RESPECT TO PRIVATE-LABEL PRODUCT RITE AID RANITIDINE

8140. Plaintiffs identified in the table below bring claims against Defendant Apotex with respect to private-label product Rite Aid ranitidine on behalf of themselves and their respective State Apotex Rite Aid Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

COUNT 472:
Negligence – Failure to Warn Through Proper Expiration Dates – California

8141. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8142. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Apotex Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8143. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8144. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8145. Under California law, manufacturers, including Defendant have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

8146. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8147. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8148. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8149. The latent injuries from which Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8150. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8151. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8152. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8153. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

8154. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8155. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 473:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

8156. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8157. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Apotex Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8158. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8159. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

8160. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

8161. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

8162. The FDA was reasonably expected to disseminate this information. No speculation

is necessary on this point because the FDA in fact did warn consumers and the medical community when they learned of these risks.

8163. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

8164. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

8165. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class mhave sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8166. The latent injuries from which Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class msuffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8167. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8168. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8169. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8170. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

8171. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8172. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 474:
Negligent Product Containers – California

8173. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8174. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Apotex Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8175. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8176. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8177. Under California law, a pharmaceutical manufacturer, including Defendant, has a

duty to exercise reasonable care in choosing and making the containers for its products.

8178. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8179. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8180. The latent injuries from which Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8181. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8182. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8183. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and

losses without adequate treatment will be significantly reduced.

8184. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

8185. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8186. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 475:
Negligent Storage and Transportation – California

8187. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8188. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Apotex Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8189. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8190. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8191. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8192. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8193. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California

Apotex Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8194. The latent injuries from which Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8195. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8196. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8197. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8198. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

8199. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8200. Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

Q. CAUSES OF ACTION AGAINST DEFENDANT APOTEX WITH RESPECT TO PRIVATE-LABEL PRODUCT WAL-ZAN RANITIDINE

8201. Plaintiffs identified in the table below bring claims against Defendant Apotex with respect to private-label product Wal-Zan ranitidine on behalf of themselves and their respective State Apotex Wal-Zan Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ

Golbenaz Bakhtiar	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1. Arizona

COUNT 476:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

8202. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8203. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8204. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8205. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-

Specific Allegations) as to Defendant.

8206. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

8207. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8208. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8209. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8210. The latent injuries from which Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8211. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8212. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8213. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8214. Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8215. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8216. Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 477:
Negligent Product Containers – Arizona

8217. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8218. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8219. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8220. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to Defendant.

8221. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8222. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8223. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8224. The latent injuries from which Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8225. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8226. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8227. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8228. Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8229. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8230. Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 478:
Negligent Storage and Transportation – Arizona

8231. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8232. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8233. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8234. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8235. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8236. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

8237. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8238. The latent injuries from which Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8239. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8240. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8241. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8242. Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8243. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8244. Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 479:
Negligence – Failure to Warn Through Proper Expiration Dates – California

8245. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8246. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8247. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8248. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8249. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

8250. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8251. Plaintiffs or their doctors would have read and heeded these warnings had they been

included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8252. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8253. The latent injuries from which Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8254. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8255. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8256. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and

losses without adequate treatment will be significantly reduced.

8257. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8258. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8259. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 480:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

8260. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8261. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8262. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8263. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

8264. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

8265. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably

expected to pool and share safety-related information and publicize risks to the medical community.

8266. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

8267. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

8268. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

8269. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8270. The latent injuries from which Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

8271. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8272. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8273. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8274. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8275. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8276. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 481:
Negligent Product Containers – California

8277. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8278. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8279. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8280. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8281. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8282. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8283. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8284. The latent injuries from which Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8285. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8286. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

8287. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8288. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8289. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8290. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 482:
Negligent Storage and Transportation – California

8291. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8292. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8293. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8294. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8295. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8296. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

8297. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8298. The latent injuries from which Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8299. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8300. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8301. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8302. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8303. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8304. Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 483:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

8305. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8306. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8307. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8308. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8309. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8310. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

8311. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8312. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8313. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8314. The latent injuries from which Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8315. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8316. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8317. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado

Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8318. Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8319. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8320. Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 484:
Medical Monitoring – Negligent Product Containers – Colorado

8321. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8322. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8323. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8324. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8325. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8326. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8327. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8328. As a direct and proximate result of this failure, excessive levels of NDMA built up

in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8329. The latent injuries from which Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8330. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8331. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8332. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8333. Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8334. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8335. Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 485:
Medical Monitoring – Negligent Storage and Transportation – Colorado

8336. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8337. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8338. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8339. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8340. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8341. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8342. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8343. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical

monitoring.

8344. The latent injuries from which Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8345. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8346. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8347. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8348. Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8349. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 486:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

8350. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of

ranitidine and injury), as if fully stated herein.

8351. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8352. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8353. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8354. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8355. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

8356. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8357. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8358. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8359. The latent injuries from which Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8360. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8361. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8362. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8363. Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8364. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8365. Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 487:
Medical Monitoring – Negligent Product Containers – Florida

8366. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8367. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8368. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8369. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8370. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8371. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8372. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8373. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8374. The latent injuries from which Plaintiffs and the Florida Apotex Wal-Zan Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8375. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8376. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8377. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8378. Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8379. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8380. Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 488:
Medical Monitoring – Negligent Storage and Transportation – Florida

8381. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8382. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"),

against Apotex (for the purposes of this Count, "Defendant").

8383. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8384. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8385. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8386. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8387. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8388. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8389. The latent injuries from which Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8390. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8391. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8392. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8393. Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8394. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Apotex Wal-Zan Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

8395. Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. West Virginia

COUNT 489:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

8396. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8397. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8398. The allegations in this Count apply to Apotex during the time period in which it

was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8399. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8400. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8401. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

8402. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8403. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8404. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8405. The latent injuries from which Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8406. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8407. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8408. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8409. Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8410. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8411. Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 490:
Medical Monitoring – Negligent Product Containers – West Virginia

8412. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8413. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8414. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8415. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8416. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8417. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8418. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8419. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8420. The latent injuries from which Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8421. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8422. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8423. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8424. Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8425. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8426. Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk

of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 491:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

8427. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8428. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Apotex Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8429. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8430. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8431. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8432. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8433. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8434. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8435. The latent injuries from which Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8436. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8437. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8438. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8439. Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8440. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Apotex Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8441. Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Apotex Wal-Zan Medical Monitoring Class members will

continue to face an unreasonable risk of injury and disability and remain undiagnosed.

R. CAUSES OF ACTION AGAINST DEFENDANT APOTEX WITH RESPECT TO PRIVATE-LABEL PRODUCT EQUATE RANITIDINE

8442. Plaintiffs identified in the table below bring claims against Defendant Apotex with respect to private-label product Equate ranitidine on behalf of themselves and their respective State Apotex Equate Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

1. Arizona

COUNT 492:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

8443. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8444. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8445. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8446. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8447. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

8448. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8449. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8450. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Apotex

Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8451. The latent injuries from which Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8452. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8453. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8454. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8455. Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8456. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8457. Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 493:
Negligent Product Containers – Arizona

8458. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8459. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8460. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8461. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8462. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8463. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8464. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8465. The latent injuries from which Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8466. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8467. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8468. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8469. Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8470. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Apotex Equate Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

8471. Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 494:
Negligent Storage and Transportation – Arizona

8472. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8473. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8474. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

8475. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8476. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8477. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8478. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8479. The latent injuries from which Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8480. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

8481. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8482. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8483. Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8484. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8485. Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Arizona Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Colorado

COUNT 495:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

8486. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8487. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8488. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8489. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8490. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

8491. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

8492. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8493. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8494. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8495. The latent injuries from which Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8496. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8497. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8498. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8499. Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8500. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8501. Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 496:
Medical Monitoring – Negligent Product Containers – Colorado

8502. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8503. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8504. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8505. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8506. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8507. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8508. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8509. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8510. The latent injuries from which Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8511. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8512. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

8513. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8514. Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8515. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8516. Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 497:
Medical Monitoring – Negligent Storage and Transportation – Colorado

8517. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8518. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8519. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8520. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8521. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8522. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8523. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8524. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8525. The latent injuries from which Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8526. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8527. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8528. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado

Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8529. Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8530. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Florida

COUNT 498:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

8531. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8532. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8533. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8534. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8535. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8536. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

8537. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8538. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8539. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8540. The latent injuries from which Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8541. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8542. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8543. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8544. Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8545. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8546. Plaintiffs and the Florida Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 499:
Medical Monitoring – Negligent Product Containers – Florida

8547. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8548. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8549. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8550. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8551. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8552. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8553. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8554. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8555. The latent injuries from which Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8556. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8557. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8558. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8559. Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8560. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8561. Plaintiffs and the Florida Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 500:
Medical Monitoring – Negligent Storage and Transportation – Florida

8562. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8563. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8564. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8565. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8566. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8567. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8568. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8569. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and

transported, and therefore Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8570. The latent injuries from which Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8571. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8572. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8573. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8574. Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Apotex Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8575. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8576. Plaintiffs and the Florida Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. West Virginia

COUNT 501:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

8577. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8578. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8579. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8580. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8581. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8582. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

8583. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8584. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

8585. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8586. The latent injuries from which Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8587. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8588. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8589. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8590. Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members

seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8591. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8592. Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 502:
Medical Monitoring – Negligent Product Containers – West Virginia

8593. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8594. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8595. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8596. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8597. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8598. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8599. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8600. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses

associated with ongoing medical monitoring.

8601. The latent injuries from which Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8602. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8603. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8604. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8605. Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8606. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8607. Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 503:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

8608. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 657-706 (describing Apotex-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8609. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Apotex Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Apotex (for the purposes of this Count, "Defendant").

8610. The allegations in this Count apply to Apotex during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8611. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8612. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8613. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8614. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8615. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8616. The latent injuries from which Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8617. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8618. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8619. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8620. Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members as frequently and appropriately as necessary.

8621. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Apotex Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8622. Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Apotex Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

S. CAUSES OF ACTION AGAINST DEFENDANT DR. REDDY'S WITH RESPECT TO PRIVATE-LABEL PRODUCT CVS HEALTH RANITIDINE

8623. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's with respect to private-label product CVS Health ranitidine on behalf of themselves and their respective State Dr. Reddy's CVS Health Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section IV, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1. California

COUNT 504:
Negligence – Failure to Warn Through Proper Expiration Dates – California

8624. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8625. This cause of action is brought by Richard Obrien, individually and on behalf of the California Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8626. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8627. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8628. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture

and distribution.

8629. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8630. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8631. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8632. The latent injuries from which Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8633. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8634. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8635. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8636. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8637. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8638. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or

established by the Court, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 505:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

8639. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8640. This cause of action is brought by Richard Obrien, individually and on behalf of the California Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8641. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8642. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

8643. Under California law, manufacturers, including Defendant, bear "a duty to convey

warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

8644. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

8645. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

8646. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

8647. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

8648. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased

risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8649. The latent injuries from which Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8650. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8651. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8652. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8653. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California

Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8654. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8655. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 506:
Negligent Product Containers – California

8656. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8657. This cause of action is brought by Richard Obrien, individually and on behalf of the California Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8658. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8659. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8660. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8661. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8662. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8663. The latent injuries from which Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is

specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8664. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8665. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8666. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8667. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8668. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8669. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 507:
Negligent Storage and Transportation – California

8670. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8671. This cause of action is brought by Richard Obrien, individually and on behalf of the California Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8672. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8673. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8674. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8675. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8676. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8677. The latent injuries from which Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

8678. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8679. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8680. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8681. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8682. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's CVS Health Medical Monitoring Class members in writing

that they may require frequent medical monitoring for the purpose of diagnosis.

8683. Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Indiana

COUNT 508:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

8684. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8685. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8686. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8687. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8688. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

8689. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8690. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8691. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8692. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8693. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8694. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8695. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8696. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8697. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8698. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 509:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

8699. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8700. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8701. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8702. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

8703. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

8704. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

8705. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

8706. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

8707. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

8708. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8709. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8710. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8711. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8712. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8713. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8714. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8715. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 510:
Negligent Product Containers – Indiana

8716. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8717. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8718. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8719. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8720. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8721. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8722. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Indiana Dr.

Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8723. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8724. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8725. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8726. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8727. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8728. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8729. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 511:
Negligent Storage and Transportation – Indiana

8730. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8731. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8732. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8733. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8734. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8735. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8736. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8737. The latent injuries from which Plaintiffs and the Indiana Dr. Reddy's CVS Health

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8738. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8739. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8740. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8741. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8742. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8743. Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Ohio

COUNT 512:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

8744. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8745. This cause of action is brought by Chris Troyan, and Patricia Hess, individually and

on behalf of the Ohio Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8746. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8747. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8748. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

8749. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8750. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8751. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8752. The latent injuries from which Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8753. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8754. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8755. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8756. Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8757. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8758. Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 513:
Negligent Product Containers – Ohio

8759. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8760. This cause of action is brought by Chris Troyan, and Patricia Hess, individually and

on behalf of the Ohio Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8761. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8762. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8763. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8764. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8765. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8766. The latent injuries from which Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8767. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8768. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8769. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8770. Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8771. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8772. Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 514:
Negligent Storage and Transportation – Ohio

8773. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8774. This cause of action is brought Chris Troyan, and Patricia Hess, individually and on behalf of the Ohio Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8775. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8776. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8777. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8778. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8779. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8780. The latent injuries from which Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8781. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8782. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

8783. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8784. Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8785. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8786. Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. West Virginia

COUNT 515:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

8787. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8788. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8789. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8790. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8791. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8792. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the

product would be unreasonably dangerous if distributed without a particular warning.

8793. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8794. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8795. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8796. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8797. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8798. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8799. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8800. Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8801. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8802. Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or

established by the Court, Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 516:
Medical Monitoring – Negligent Product Containers – West Virginia

8803. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8804. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8805. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8806. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8807. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

8808. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8809. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8810. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8811. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8812. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8813. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8814. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8815. Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8816. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8817. Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 517:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

8818. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8819. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8820. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8821. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8822. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8823. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8824. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8825. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8826. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8827. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8828. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8829. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia

Dr. Reddy's CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8830. Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

8831. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8832. Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

T. CAUSES OF ACTION AGAINST DEFENDANT DR. REDDY'S WITH RESPECT TO PRIVATE-LABEL PRODUCT WAL-ZAN

8833. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's with respect to private-label product Wal-Zan ranitidine on behalf of themselves and their respective State Dr. Reddy's Wal-Zan Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1. Arizona

COUNT 518:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

8834. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8835. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8836. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8837. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8838. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

8839. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8840. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8841. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Dr. Reddy's

Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8842. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8843. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8844. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8845. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8846. Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8847. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8848. Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 519:
Negligent Product Containers – Arizona

8849. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8850. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8851. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8852. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8853. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8854. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8855. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8856. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8857. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8858. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8859. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8860. Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8861. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that

they may require frequent medical monitoring for the purpose of diagnosis.

8862. Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 520:
Negligent Storage and Transportation – Arizona

8863. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8864. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8865. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

8866. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8867. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8868. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8869. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8870. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8871. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

8872. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8873. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8874. Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8875. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8876. Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Arizona Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 521:
Negligence – Failure to Warn Through Proper Expiration Dates – California

8877. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8878. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8879. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8880. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8881. Under California law, manufacturers have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

8882. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8883. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8884. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8885. The latent injuries from which Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8886. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8887. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8888. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8889. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8890. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8891. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products.

Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 522:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

8892. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8893. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8894. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8895. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

8896. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

8897. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

8898. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

8899. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

8900. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

8901. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Dr.

Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8902. The latent injuries from which Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8903. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8904. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8905. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8906. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8907. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8908. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 523:
Negligent Product Containers – California

8909. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8910. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8911. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8912. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8913. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8914. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8915. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8916. The latent injuries from which Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8917. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8918. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8919. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8920. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8921. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all California Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8922. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 524:
Negligent Storage and Transportation – California

8923. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8924. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8925. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8926. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8927. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8928. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8929. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, which Plaintiffs consumed. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8930. The latent injuries from which Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8931. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8932. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8933. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8934. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8935. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8936. Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class have

an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 525:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

8937. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8938. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8939. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8940. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8941. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8942. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

8943. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8944. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8945. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8946. The latent injuries from which Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8947. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8948. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8949. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8950. Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8951. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that

they may require frequent medical monitoring for the purpose of diagnosis.

8952. Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 526:
Medical Monitoring – Negligent Product Containers – Colorado

8953. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8954. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8955. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

8956. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

8957. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8958. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

8959. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

8960. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8961. The latent injuries from which Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8962. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

8963. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8964. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8965. Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8966. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8967. Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 527:
Medical Monitoring – Negligent Storage and Transportation – Colorado

8968. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8969. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8970. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8971. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

8972. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8973. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

8974. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

8975. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8976. The latent injuries from which Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8977. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

8978. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

8979. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8980. Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8981. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 528:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

8982. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8983. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

8984. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

8985. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

8986. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

8987. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light

of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

8988. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

8989. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

8990. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8991. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

8992. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

8993. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

8994. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

8995. Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

8996. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

8997. Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 529:
Medical Monitoring – Negligent Product Containers – Florida

8998. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

8999. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9000. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9001. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9002. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9003. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9004. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9005. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9006. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9007. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9008. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9009. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr.

Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9010. Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9011. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9012. Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 530:
Medical Monitoring – Negligent Storage and Transportation – Florida

9013. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9014. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9015. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9016. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9017. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9018. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9019. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9020. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9021. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9022. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9023. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9024. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9025. Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members

seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9026. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9027. Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

U. CAUSES OF ACTION AGAINST DEFENDANT DR. REDDY'S WITH RESPECT TO PRIVATE-LABEL PRODUCT EQUATE RANITIDINE

9028. Plaintiffs identified in the table below bring claims against Defendant Dr. Reddy's with respect to private-label product Equate ranitidine on behalf of themselves and their respective State Dr. Reddy's Equate Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B

and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

1. Arizona

COUNT 531:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

9029. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9030. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9031. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9032. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9033. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9034. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9035. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9036. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9037. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9038. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9039. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9040. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9041. Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9042. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Arizona Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9043. Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 532:
Negligent Product Containers – Arizona

9044. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9045. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9046. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9047. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9048. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9049. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9050. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9051. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9052. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9053. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9054. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9055. Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9056. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9057. Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members will continue

to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 533:
Negligent Storage and Transportation – Arizona

9058. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9059. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9060. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9061. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9062. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9063. Defendant breached this duty by failing to implement or enforce policies to ensure

Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9064. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9065. The latent injuries from which Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9066. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9067. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9068. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and

losses without adequate treatment will be significantly reduced.

9069. Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9070. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9071. Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 534:
Negligence – Failure to Warn Through Proper Expiration Dates – California

9072. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9073. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9074. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9075. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9076. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

9077. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9078. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9079. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9080. The latent injuries from which Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9081. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9082. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9083. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr.

Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9084. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9085. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9086. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 535:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

9087. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9088. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9089. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9090. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

9091. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

9092. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may

fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9093. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

9094. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

9095. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

9096. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9097. The latent injuries from which Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9098. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9099. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9100. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9101. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9102. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Equate Medical Monitoring Class members in writing that

they may require frequent medical monitoring for the purpose of diagnosis.

9103. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 536:
Negligent Product Containers – California

9104. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9105. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9106. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

9107. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9108. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9109. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9110. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9111. The latent injuries from which Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9112. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9113. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9114. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9115. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9116. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9117. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 537:
Negligent Storage and Transportation – California

9118. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9119. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9120. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9121. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9122. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9123. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

9124. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9125. The latent injuries from which Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9126. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9127. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9128. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9129. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9130. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9131. Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 538:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

9132. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9133. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9134. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9135. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9136. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9137. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

9138. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9139. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9140. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9141. The latent injuries from which Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9142. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9143. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9144. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Dr.

Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9145. Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9146. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9147. Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 539:
Medical Monitoring – Negligent Product Containers – Colorado

9148. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9149. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9150. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9151. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9152. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9153. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9154. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9155. As a direct and proximate result of this failure, excessive levels of NDMA built up

in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9156. The latent injuries from which Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9157. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9158. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9159. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9160. Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Dr. Reddy's Equate Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9161. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9162. Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 540:
Medical Monitoring – Negligent Storage and Transportation – Colorado

9163. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9164. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9165. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9166. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9167. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9168. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9169. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9170. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses

and expenses associated with ongoing medical monitoring.

9171. The latent injuries from which Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9172. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9173. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9174. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9175. Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9176. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 541:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

9177. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use

of ranitidine and injury), as if fully stated herein.

9178. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9179. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9180. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9181. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9182. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9183. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9184. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9185. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9186. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9187. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9188. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9189. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9190. Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9191. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9192. Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 542:
Medical Monitoring – Negligent Product Containers – Florida

9193. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9194. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9195. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9196. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9197. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9198. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9199. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9200. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9201. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Equate

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9202. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9203. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9204. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9205. Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9206. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9207. Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 543:
Medical Monitoring – Negligent Storage and Transportation – Florida

9208. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9209. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9210. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9211. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9212. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9213. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9214. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9215. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9216. The latent injuries from which Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9217. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9218. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9219. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9220. Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9221. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Dr. Reddy's Equate Medical Monitoring Class members in writing that they

may require frequent medical monitoring for the purpose of diagnosis.

9222. Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. West Virginia

COUNT 544:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

9223. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9224. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9225. The allegations in this Count apply to Dr. Reddy's during the time period in which

it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9226. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9227. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9228. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

9229. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9230. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9231. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9232. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9233. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9234. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9235. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9236. Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9237. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9238. Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 545:
Medical Monitoring – Negligent Product Containers – West Virginia

9239. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9240. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9241. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9242. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9243. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9244. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9245. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9246. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9247. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9248. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9249. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9250. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9251. Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9252. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9253. Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class

have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 546:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

9254. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 707-44 (describing Dr. Reddy's-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9255. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Dr. Reddy's Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Dr. Reddy's (for the purposes of this Count, "Defendant").

9256. The allegations in this Count apply to Dr. Reddy's during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9257. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9258. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9259. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9260. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9261. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9262. The latent injuries from which Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9263. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9264. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9265. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9266. Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9267. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Dr. Reddy's Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9268. Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing

Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Dr. Reddy's Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

V. CAUSES OF ACTION AGAINST DEFENDANT PERRIGO WITH RESPECT TO PRIVATE-LABEL PRODUCT CVS HEALTH RANITIDINE

9269. Plaintiffs identified in the table below bring claims against Defendant Perrigo with respect to private-label product CVS Health ranitidine on behalf of themselves and their respective State Perrigo CVS Health Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1. California

COUNT 547:
Negligence – Failure to Warn Through Proper Expiration Dates – California

9270. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9271. This cause of action is brought by Richard Obrien, individually and on behalf of the California Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9272. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9273. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9274. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

9275. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9276. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

9277. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9278. The latent injuries from which Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9279. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9280. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9281. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9282. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class

members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9283. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9284. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 548:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

9285. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9286. This cause of action is brought by Richard Obrien, individually and on behalf of the California Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9287. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9288. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

9289. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

9290. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9291. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

9292. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

9293. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

9294. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9295. The latent injuries from which Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9296. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9297. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9298. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9299. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9300. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9301. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk

of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 549:
Negligent Product Containers – California

9302. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9303. This cause of action is brought by Richard Obrien, individually and on behalf of the California Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9304. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9305. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9306. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9307. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9308. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9309. The latent injuries from which Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9310. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9311. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9312. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California

Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9313. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9314. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9315. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 550:
Negligent Storage and Transportation – California

9316. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9317. This cause of action is brought by Richard Obrien, individually and on behalf of the California Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9318. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9319. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9320. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9321. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9322. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and

transported, and therefore Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9323. The latent injuries from which Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9324. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9325. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9326. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9327. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo CVS Health Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9328. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9329. Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Indiana

COUNT 551:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

9330. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9331. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9332. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9333. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9334. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

9335. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9336. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9337. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9338. The latent injuries from which Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9339. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9340. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9341. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9342. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9343. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9344. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 552:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

9345. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9346. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9347. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9348. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

9349. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

9350. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9351. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

9352. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

9353. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

9354. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9355. The latent injuries from which Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9356. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9357. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9358. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9359. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9360. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9361. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 553:
Negligent Product Containers – Indiana

9362. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9363. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9364. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9365. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to Defendant.

9366. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9367. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9368. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9369. The latent injuries from which Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9370. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9371. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9372. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9373. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9374. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9375. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 554:
Negligent Storage and Transportation – Indiana

9376. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9377. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9378. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9379. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9380. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9381. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9382. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9383. The latent injuries from which Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9384. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9385. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9386. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9387. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9388. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9389. Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Ohio

COUNT 555:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

9390. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9391. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9392. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9393. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9394. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

9395. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9396. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

9397. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9398. The latent injuries from which Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9399. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9400. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9401. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9402. Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members

seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9403. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9404. Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 556:
Negligent Product Containers – Ohio

9405. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9406. This cause of action is brought by Chris Troyan and Patricia Hess,individually and on behalf of the Ohio Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9407. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9408. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9409. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9410. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9411. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9412. The latent injuries from which Plaintiffs and the Ohio Perrigo CVS Health Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9413. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9414. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9415. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9416. Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9417. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9418. Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 557:
Negligent Storage and Transportation – Ohio

9419. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9420. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio Perrigo CVS Health Medical Monitoring Class (for the purposes of this

Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9421. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9422. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9423. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9424. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9425. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9426. The latent injuries from which Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9427. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9428. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9429. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9430. Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9431. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9432. Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. West Virginia

COUNT 558:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

9433. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9434. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9435. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9436. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9437. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9438. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

9439. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9440. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9441. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9442. The latent injuries from which Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9443. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9444. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9445. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9446. Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9447. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Perrigo CVS Health Medical Monitoring Class members in writing

that they may require frequent medical monitoring for the purpose of diagnosis.

9448. Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 559:
Medical Monitoring – Negligent Product Containers – West Virginia

9449. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9450. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9451. The allegations in this Count apply to Perrigo during the time period in which it

was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9452. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9453. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9454. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9455. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9456. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9457. The latent injuries from which Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9458. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9459. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9460. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9461. Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9462. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9463. Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing

Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 560:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

9464. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9465. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Perrigo CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9466. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9467. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9468. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9469. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9470. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9471. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9472. The latent injuries from which Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9473. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9474. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9475. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9476. Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9477. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Perrigo CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9478. Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Perrigo CVS Health Medical Monitoring

Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

W. CAUSES OF ACTION AGAINST DEFENDANT PERRIGO WITH RESPECT TO PRIVATE-LABEL PRODUCT RITE AID RANITIDINE

9479. Plaintiffs identified in the table below bring claims against Defendant Perrigo with respect to private-label product Rite Aid ranitidine on behalf of themselves and their respective State Perrigo Rite Aid Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

COUNT 561:
Negligence – Failure to Warn Through Proper Expiration Dates – California

9480. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9481. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Perrigo Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9482. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9483. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9484. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

9485. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9486. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9487. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

9488. The latent injuries from which Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9489. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9490. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9491. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9492. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

9493. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9494. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 562:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

9495. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of

ranitidine and injury), as if fully stated herein.

9496. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Perrigo Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9497. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9498. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

9499. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

9500. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9501. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

9502. Because federal law requires generic drug labels to largely match branded drug

labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

9503. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

9504. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9505. The latent injuries from which Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9506. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9507. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9508. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9509. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

9510. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9511. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 563:
Negligent Product Containers – California

9512. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9513. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Perrigo Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9514. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9515. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9516. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9517. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9518. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9519. The latent injuries from which Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9520. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9521. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9522. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9523. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

9524. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9525. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 564:
Negligent Storage and **Transportation** – **California**

9526. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9527. This cause of action is brought by Golbenaz Bakhtiar and Richard Obrien, individually and on behalf of the California Perrigo Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9528. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9529. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9530. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9531. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9532. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9533. The latent injuries from whiyou mch Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9534. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9535. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9536. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9537. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

9538. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9539. Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

X. CAUSES OF ACTION AGAINST DEFENDANT PERRIGO WITH RESPECT TO PRIVATE-LABEL PRODUCT WAL-ZAN RANITIDINE

9540. Plaintiffs identified in the table below bring claims against Defendant Perrigo with respect to private-label product Wal-Zan ranitidine on behalf of themselves and their respective State Perrigo Wal-Zan Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhtiar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO

Ronald Ragis	FL

1. Arizona

COUNT 565:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

9541. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9542. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9543. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9544. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9545. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light

of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9546. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9547. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9548. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9549. The latent injuries from which Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9550. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

9551. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9552. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9553. Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9554. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9555. Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 566:
Negligent Product Containers – Arizona

9556. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9557. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9558. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9559. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9560. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9561. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9562. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9563. The latent injuries from which Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9564. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9565. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9566. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9567. Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9568. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9569. Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 567:
Negligent Storage and Transportation – Arizona

9570. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9571. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9572. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9573. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9574. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9575. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9576. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal

Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9577. The latent injuries from which Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9578. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9579. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9580. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9581. Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Perrigo Wal-Zan Medical

Monitoring Class members as frequently and appropriately as necessary.

9582. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9583. Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 568:
Negligence – Failure to Warn Through Proper Expiration Dates – California

9584. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9585. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9586. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9587. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9588. Under California law, manufacturers, like Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

9589. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9590. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9591. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo

Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9592. The latent injuries from which Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9593. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9594. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9595. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9596. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9597. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9598. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 569:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

9599. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9600. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9601. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9602. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

9603. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

9604. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9605. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

9606. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

9607. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

9608. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9609. The latent injuries from which Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9610. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9611. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9612. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9613. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9614. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9615. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will continue to

face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 570:
Negligent Product Containers – California

9616. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9617. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9618. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9619. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9620. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9621. Defendant breached this duty by failing to utilize containers that would minimize

the NDMA produced in its Ranitidine-Containing Products.

9622. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9623. The latent injuries from which Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9624. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9625. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9626. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9627. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members

seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9628. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9629. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 571:
Negligent Storage and Transportation – California

9630. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9631. This cause of action is brought by Golbenaz Bakhtiar and Jonathan Ferguson, individually and on behalf of the California Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9632. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9633. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9634. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9635. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9636. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with

ongoing medical monitoring.

9637. The latent injuries from which Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9638. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9639. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9640. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9641. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9642. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9643. Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 572:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

9644. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of

ranitidine and injury), as if fully stated herein.

9645. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9646. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9647. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9648. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9649. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

9650. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9651. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9652. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Perrigo

Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9653. The latent injuries from which Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9654. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9655. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9656. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9657. Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9658. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9659. Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 573:
Medical Monitoring – Negligent Product Containers – Colorado

9660. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9661. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9662. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9663. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9664. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9665. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9666. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9667. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9668. The latent injuries from which Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9669. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9670. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9671. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9672. Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9673. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9674. Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 574:
Medical Monitoring – Negligent Storage and Transportation – Colorado

9675. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9676. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9677. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9678. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9679. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9680. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9681. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9682. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9683. The latent injuries from which Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

9684. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9685. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9686. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9687. Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9688. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 575:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

9689. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9690. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9691. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

9692. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9693. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9694. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9695. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9696. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9697. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9698. The latent injuries from which Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not

generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9699. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9700. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9701. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9702. Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9703. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9704. Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 576:
Medical Monitoring – Negligent Product Containers – Florida

9705. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9706. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9707. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9708. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9709. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9710. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9711. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9712. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9713. The latent injuries from which Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9714. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9715. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9716. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9717. Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9718. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9719. Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 577:
Medical Monitoring – Negligent Storage and Transportation – Florida

9720. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9721. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Perrigo Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9722. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9723. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9724. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9725. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9726. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9727. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9728. The latent injuries from which Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9729. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9730. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9731. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9732. Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

9733. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Perrigo Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9734. Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Perrigo Wal-Zan Medical Monitoring Class members will continue to

face an unreasonable risk of injury and disability and remain undiagnosed.

Y. CAUSES OF ACTION AGAINST DEFENDANT PERRIGO WITH RESPECT TO PRIVATE-LABEL PRODUCT EQUATE RANITIDINE

9735. Plaintiffs identified in the table below bring claims against Defendant Perrigo with respect to private-label product Equate ranitidine on behalf of themselves and their respective State Perrigo Equate Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

1. Arizona

COUNT 578:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

9736. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9737. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9738. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9739. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9740. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9741. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9742. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9743. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9744. The latent injuries from which Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9745. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9746. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9747. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9748. Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9749. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9750. Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 579:
Negligent Product Containers – Arizona

9751. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9752. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9753. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9754. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9755. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9756. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9757. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9758. The latent injuries from which Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals

exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9759. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9760. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9761. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9762. Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9763. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Arizona Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9764. Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 580:
Negligent Storage and Transportation – Arizona

9765. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9766. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9767. The allegations in this Count apply to Perrigo during the time period in which it

was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9768. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9769. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9770. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9771. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9772. The latent injuries from which Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9773. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9774. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9775. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9776. Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9777. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9778. Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 581:
Negligence – Failure to Warn Through Proper Expiration Dates – California

9779. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9780. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9781. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9782. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9783. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

9784. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9785. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9786. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9787. The latent injuries from which Plaintiffs and the California Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9788. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9789. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9790. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9791. Plaintiffs and the California Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9792. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9793. Plaintiffs and the California Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 582:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

9794. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9795. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9796. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9797. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

9798. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

9799. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9800. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

9801. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

9802. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

9803. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Perrigo

Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9804. The latent injuries from which Plaintiffs and the California Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9805. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9806. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9807. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9808. Plaintiffs and the California Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9809. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9810. Plaintiffs and the California Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 583:
Negligent Product Containers – California

9811. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9812. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9813. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9814. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9815. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9816. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9817. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9818. The latent injuries from which Plaintiffs and the California Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9819. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9820. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9821. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9822. Plaintiffs and the California Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9823. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Equate Medical Monitoring Class members in writing that they

may require frequent medical monitoring for the purpose of diagnosis.

9824. Plaintiffs and the California Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 584:
Negligent Storage and Transportation – California

9825. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9826. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9827. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in

paragraphs 172-84, which are incorporated by reference.

9828. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9829. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9830. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9831. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9832. The latent injuries from which Plaintiffs and the California Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9833. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

9834. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9835. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9836. Plaintiffs and the California Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9837. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9838. Plaintiffs and the California Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Colorado

COUNT 585:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

9839. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9840. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9841. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9842. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9843. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

9844. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

9845. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9846. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9847. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9848. The latent injuries from which Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9849. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9850. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9851. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9852. Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9853. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9854. Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 586:
Medical Monitoring – Negligent Product Containers – Colorado

9855. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9856. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9857. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9858. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9859. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9860. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9861. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9862. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9863. The latent injuries from which Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9864. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9865. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

9866. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9867. Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9868. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9869. Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 587:
Medical Monitoring – Negligent Storage and Transportation – Colorado

9870. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9871. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9872. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9873. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9874. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9875. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9876. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9877. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9878. The latent injuries from which Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9879. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9880. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9881. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado

Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9882. Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9883. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Florida

COUNT 588:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

9884. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9885. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9886. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9887. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9888. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9889. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9890. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9891. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9892. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9893. The latent injuries from which Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9894. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9895. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9896. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9897. Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9898. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9899. Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 589:
Medical Monitoring – Negligent Product Containers – Florida

9900. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9901. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9902. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9903. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9904. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9905. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9906. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9907. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9908. The latent injuries from which Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9909. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9910. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9911. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9912. Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9913. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9914. Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 590:
Medical Monitoring – Negligent Storage and Transportation – Florida

9915. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9916. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9917. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9918. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9919. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9920. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9921. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9922. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and

transported, and therefore Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9923. The latent injuries from which Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9924. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9925. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9926. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9927. Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9928. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9929. Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. West Virginia

COUNT 591:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

9930. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9931. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9932. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9933. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

9934. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9935. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

9936. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9937. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the

use of the Ranitidine-Containing Products.

9938. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9939. The latent injuries from which Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9940. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9941. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9942. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9943. Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members

seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9944. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9945. Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 592:
Medical Monitoring – Negligent Product Containers – West Virginia

9946. Plaintiffs incorporate by reference each allegation set forth in paragraphs 41–153 (describing Generic Manufacturer Defendants), 432–37 (describing the regulatory framework for generics), 322–42 (describing the recall of ranitidine), 385–97 (describing the breakdown of ranitidine before ingestion), 405–08 (describing Defendant's knowledge), 409–31 (describing the

regulatory framework for drug manufacturers), and 455–66 (describing Plaintiffs' use of ranitidine and injury) as if fully stated herein.

9947. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9948. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9949. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9950. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

9951. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9952. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

9953. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

9954. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9955. The latent injuries from which Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9956. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9957. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9958. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9959. Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9960. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9961. Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 593:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

9962. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 745-95 (describing Perrigo-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9963. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Perrigo Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Perrigo (for the purposes of this Count, "Defendant").

9964. The allegations in this Count apply to Perrigo during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9965. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

9966. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

9967. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

9968. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

9969. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic

Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9970. The latent injuries from which Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9971. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9972. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9973. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9974. Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring

Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members as frequently and appropriately as necessary.

9975. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Perrigo Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9976. Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Perrigo Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

Z. CAUSES OF ACTION AGAINST DEFENDANT STRIDES WITH RESPECT TO PRIVATE-LABEL PRODUCT CVS HEALTH RANITIDINE

9977. Plaintiffs identified in the table below bring claims against Defendant Strides with respect to private-label product CVS Health ranitidine on behalf of themselves and their respective State Strides CVS Health Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**

Richard Obrien	CA
Rebecca Sizemore	IN
Chris Troyan	OH
Patricia Hess	OH
Mynetta Hastings	WV

1. California

COUNT 594:
Negligence – Failure to Warn Through Proper Expiration Dates – California

9978. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9979. This cause of action is brought by Richard Obrien, individually and on behalf of the California Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

9980. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9981. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-

Specific Allegations) as to Defendant.

9982. Under California law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

9983. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

9984. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

9985. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

9986. The latent injuries from which Plaintiffs and the California Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

9987. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

9988. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

9989. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

9990. Plaintiffs and the California Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

9991. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

9992. Plaintiffs and the California Strides CVS Health Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT _595:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

9993. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

9994. This cause of action is brought by Richard Obrien, individually and on behalf of the California Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

9995. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

9996. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-

Specific Allegations) as to Defendant.

9997. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

9998. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

9999. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

10000. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

10001. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

10002. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10003. The latent injuries from which Plaintiffs and the California Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10004. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10005. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10006. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10007. Plaintiffs and the California Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides CVS Health Medical

Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10008. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10009. Plaintiffs and the California Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 596:
Negligent Product Containers – California

10010. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10011. This cause of action is brought by Richard Obrien, individually and on behalf of the California Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10012. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10013. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10014. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10015. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10016. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10017. The latent injuries from which Plaintiffs and the California Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for

individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10018. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10019. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10020. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10021. Plaintiffs and the California Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10022. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all California Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10023. Plaintiffs and the California Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 597:
Negligent Storage and Transportation – California

10024. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10025. This cause of action is brought by Richard Obrien, individually and on behalf of the California Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10026. The allegations in this Count apply to Strides during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10027. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10028. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10029. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10030. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10031. The latent injuries from which Plaintiffs and the California Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10032. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10033. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10034. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10035. Plaintiffs and the California Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10036. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10037. Plaintiffs and the California Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Indiana

COUNT 598:
Negligence – Failure to Warn Through Proper Expiration Dates – Indiana

10038. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10039. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10040. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10041. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10042. Under Indiana law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

10043. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10044. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10045. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10046. The latent injuries from which Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10047. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10048. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10049. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10050. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10051. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10052. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 599:
Negligence – Failure to Warn Consumers Through the FDA – Indiana

10053. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10054. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10055. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10056. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

10057. Indiana law allows a plaintiff to "state[] plausible claims for relief under state law

based on an alleged failure to warn the FDA." *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015), *on reconsideration*, No. 1:12-CV-417 RLM, 2016 WL 2588807 (N.D. Ind. May 5, 2016) (rejecting causation). Failures to warn are governed by negligence principles. Ind. Code Ann. § 34-20-2-2. ("[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing the warnings or instructions.")

10058. Defendant ultimately owed this duty to warn to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers "fail[] to exercise reasonable care under the circumstances," Ind. Code Ann. § 34-20-2-2, in warning consumers if they fail to warn the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

10059. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

10060. Because federal law requires generic drug labels to largely match branded drug labels, Defendant was not able to warn consumers directly of the cancer risks of ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Generic Manufacturer Defendants failed to warn anyone through any medium.

10061. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting. This failure breached their duty of reasonable care.

10062. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10063. The latent injuries from which Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10064. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10065. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10066. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10067. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10068. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10069. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 600:
Negligent Product Containers – Indiana

10070. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10071. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10072. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10073. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10074. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10075. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10076. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10077. The latent injuries from which Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10078. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10079. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10080. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10081. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10082. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10083. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 601:
Negligent Storage and Transportation – Indiana

10084. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10085. This cause of action is brought by Rebecca Sizemore, individually and on behalf of the Indiana Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10086. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10087. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10088. Under Indiana law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10089. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10090. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10091. The latent injuries from which Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10092. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10093. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10094. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10095. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10096. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10097. Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. **Ohio**

COUNT 602:
Strict Products Liability – Failure to Warn Through Proper Expiration Dates – Ohio

10098. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10099. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10100. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10101. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-

Specific Allegations) as to Defendant.

10102. Under Ohio law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

10103. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10104. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10105. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10106. The latent injuries from which Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10107. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10108. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10109. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10110. Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10111. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10112. Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 603:
Negligent Product Containers – Ohio

10113. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10114. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10115. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10116. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-

Specific Allegations) as to Defendant.

10117. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10118. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10119. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10120. The latent injuries from which Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10121. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10122. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10123. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10124. Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10125. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10126. Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 604:
Negligent Storage and Transportation – Ohio

10127. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10128. This cause of action is brought by Chris Troyan and Patricia Hess, individually and on behalf of the Ohio Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10129. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10130. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10131. Under Ohio law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10132. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10133. As a direct and proximate result of these systematic failures, excessive levels of

NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and thefore Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10134. The latent injuries from which Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10135. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10136. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10137. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10138. Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10139. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10140. Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. **West Virginia**

COUNT 605:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

10141. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before

ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10142. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10143. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10144. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10145. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10146. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

10147. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10148. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10149. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10150. The latent injuries from which Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10151. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10152. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10153. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10154. Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10155. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10156. Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 606:
Medical Monitoring – Negligent Product Containers – West Virginia

10157. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10158. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10159. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10160. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10161. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10162. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10163. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10164. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia

Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10165. The latent injuries from which Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10166. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10167. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10168. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10169. Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust

fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10170. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10171. Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 607:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

10172. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10173. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides CVS Health Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10174. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10175. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10176. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10177. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10178. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10179. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

10180. The latent injuries from which Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10181. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10182. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10183. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10184. Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members as frequently and appropriately as necessary.

10185. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides CVS Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10186. Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides CVS Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

AA. CAUSES OF ACTION AGAINST DEFENDANT STRIDES WITH RESPECT TO PRIVATE-LABEL PRODUCT RITE AID RANITIDINE

10187. Plaintiffs identified in the table below bring claims against Defendant Strides with respect to private-label product Rite Aid ranitidine on behalf of themselves and their respective State Strides Rite Aid Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Richard Obrien	CA

COUNT 608:
Negligence – Failure to Warn Through Proper Expiration Dates – California

10188. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10189. This cause of action is brought by Golbenaz Bakhitar and Richard Obrien, individually and on behalf of the California Strides Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10190. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10191. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10192. Under California law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10193. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10194. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10195. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10196. The latent injuries from which Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10197. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10198. The available monitoring regime is reasonably necessary according to

contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10199. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10200. Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

10201. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10202. Plaintiffs and the California Strides Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 609:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

10203. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10204. This cause of action is brought by Golbenaz Bakhitar and Richard Obrien, individually and on behalf of the California Strides Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10205. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10206. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

10207. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413,

429, *as modified* (Feb. 3, 2014).

10208. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

10209. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

10210. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

10211. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

10212. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10213. The latent injuries from which Plaintiffs and the California Strides Rite Aid

Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10214. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10215. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10216. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10217. Plaintiffs and the California Strides Rite Aid Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Rite Aid Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Rite Aid Health Medical Monitoring Class members as frequently and appropriately as necessary.

10218. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Rite Aid Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10219. Plaintiffs and the California Strides Rite Aid Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Rite Aid Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 610:
Negligent Product Containers – California

10220. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10221. This cause of action is brought by Golbenaz Bakhitar and Richard Obrien, individually and on behalf of the California Strides Rite Aid Medical Monitoring Class (for the

purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10222. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10223. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10224. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10225. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10226. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10227. The latent injuries from which Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10228. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10229. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10230. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10231. Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

10232. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10233. Plaintiffs and the California Strides Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 611:
Negligent Storage and Transportation – California

10234. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10235. This cause of action is brought by Golbenaz Bakhitar and Richard Obrien, individually and on behalf of the California Strides Rite Aid Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10236. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10237. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10238. Under California law, a pharmaceutical manufacturer, including Defendant, has a

duty to exercise reasonable care in transporting and storing products.

10239. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10240. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10241. The latent injuries from which Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10242. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10243. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10244. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10245. Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members as frequently and appropriately as necessary.

10246. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Rite Aid Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10247. Plaintiffs and the California Strides Rite Aid Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Rite Aid Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

BB. CAUSES OF ACTION AGAINST DEFENDANT STRIDES WITH RESPECT TO PRIVATE-LABEL PRODUCT WAL-ZAN RANITIDINE

10248. Plaintiffs identified in the table below bring claims against Defendant Strides with respect to private-label product Wal-Zan ranitidine on behalf of themselves and their respective State Strides Wal-Zan Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Golbenaz Bakhitar	CA
Jonathan Ferguson	CA
Jeffrey Pisano	CO
Ronald Ragan	CO
Ronald Ragis	FL

1. Arizona

COUNT 612:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

10249. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of

ranitidine and injury), as if fully stated herein.

10250. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10251. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10252. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10253. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10254. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10255. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10256. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of

developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10257. The latent injuries from which Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10258. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10259. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10260. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10261. Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Wal-Zan Medical

Monitoring Class members as frequently and appropriately as necessary.

10262. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10263. Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 613:
Negligent Product Containers – Arizona

10264. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of

ranitidine and injury), as if fully stated herein.

10265. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Strides Wal-Zan Medical Monitoring Class(for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10266. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10267. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10268. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10269. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10270. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10271. The latent injuries from which Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the

absence of exposure to this risk of harm.

10272. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10273. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10274. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10275. Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10276. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10277. Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 614:
Negligent Storage and Transportation – Arizona

10278. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10279. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10280. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10281. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10282. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10283. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10284. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10285. The latent injuries from which Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10286. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10287. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10288. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10289. Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10290. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10291. Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Wal-Zan Medical Monitoring Class members will continue to

face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 615:
Negligence – Failure to Warn Through Proper Expiration Dates – California

10292. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10293. This cause of action is brought by Golbenaz Bakhitar and Jonathan Ferguson, individually and on behalf of the California Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10294. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10295. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10296. Under California law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light

of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10297. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10298. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10299. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10300. The latent injuries from which Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10301. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

10302. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10303. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10304. Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10305. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10306. Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 616:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

10307. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10308. This cause of action is brought by Golbenaz Bakhitar and Jonathan Ferguson, individually and on behalf of the California Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10309. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10310. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

10311. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes

"a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

10312. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

10313. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community when they learned of these risks.

10314. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

10315. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

10316. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer

economic losses and expenses associated with ongoing medical monitoring.

10317. The latent injuries from which Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10318. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10319. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10320. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10321. Plaintiffs and the California Strides Wal-Zan Health Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Wal-Zan Health Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Wal-Zan Health Medical Monitoring Class members as frequently and appropriately as necessary.

10322. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Wal-Zan Health Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10323. Plaintiffs and the California Strides Wal-Zan Health Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Wal-Zan Health Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 617:
Negligent Product Containers – California

10324. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of

ranitidine and injury), as if fully stated herein.

10325. This cause of action is brought by Golbenaz Bakhitar and Jonathan Ferguson, individually and on behalf of the California Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10326. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10327. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10328. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10329. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10330. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10331. The latent injuries from which Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally

recommended in the absence of exposure to this risk of harm.

10332. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10333. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10334. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10335. Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10336. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10337. Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 618:
Negligent Storage and Transportation – California

10338. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10339. This cause of action is brought by Golbenaz Bakhitar and Jonathan Ferguson, individually and on behalf of the California Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10340. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10341. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10342. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10343. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10344. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10345. The latent injuries from which Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10346. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10347. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10348. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10349. Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10350. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10351. Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Wal-Zan Medical Monitoring Class members will continue to

face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 619:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

10352. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10353. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10354. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10355. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10356. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10357. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

10358. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10359. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10360. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10361. The latent injuries from which Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10362. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10363. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10364. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10365. Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10366. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10367. Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 620:
Medical Monitoring – Negligent Product Containers – Colorado

10368. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10369. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10370. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10371. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10372. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

10373. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10374. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10375. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10376. The latent injuries from which Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10377. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10378. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10379. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10380. Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10381. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10382. Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 621:
Medical Monitoring – Negligent Storage and Transportation – Colorado

10383. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10384. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10385. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10386. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10387. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10388. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10389. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and

humidity.

10390. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10391. The latent injuries from which Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10392. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10393. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10394. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10395. Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10396. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 622:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

10397. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory

framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10398. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10399. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10400. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10401. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10402. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10403. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe

when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10404. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10405. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10406. The latent injuries from which Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10407. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10408. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10409. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10410. Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10411. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10412. Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 623:
Medical Monitoring – Negligent Product Containers – Florida

10413. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10414. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10415. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10416. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10417. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10418. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10419. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10420. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10421. The latent injuries from which Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10422. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10423. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10424. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10425. Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members as frequently and appropriately as necessary.

10426. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10427. Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 624:
Medical Monitoring – Negligent Storage and Transportation – Florida

10428. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify

FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10429. This cause of action is brought by Ronald Ragis, individually and on behalf of the Florida Strides Wal-Zan Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10430. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10431. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10432. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10433. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10434. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10435. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members have sustained a significantly

increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10436. The latent injuries from which Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10437. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10438. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10439. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10440. Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Wal-Zan Medical

Monitoring Class members as frequently and appropriately as necessary.

10441. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Wal-Zan Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10442. Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Wal-Zan Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

CC. CAUSES OF ACTION AGAINST DEFENDANT STRIDES WITH RESPECT TO PRIVATE-LABEL PRODUCT EQUATE RANITIDINE

10443. Plaintiffs identified in the table below bring claims against Defendant Strides with respect to private-label product Equate ranitidine on behalf of themselves and their respective State Strides Equate Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.B and the allegations set forth in Section VI, *supra*, into their respective claims below.

Plaintiff Name	**State of Usage**
Tangie Sims	AZ
Jonathan Ferguson	CA
Jeffrey Pisano	CO

Ronald Ragan	CO
Michael Tomlinson	FL
Mynetta Hastings	WV

1. Arizona

COUNT 625:
Negligence – Failure to Warn Through Proper Expiration Dates – Arizona

10444. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10445. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10446. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10447. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10448. Under Arizona law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10449. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10450. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10451. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10452. The latent injuries from which Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10453. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10454. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10455. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10456. Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10457. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10458. Plaintiffs and the Arizona Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 626:
Negligent Product Containers – Arizona

10459. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10460. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10461. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10462. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10463. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10464. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10465. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10466. The latent injuries from which Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10467. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10468. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10469. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides

Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10470. Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10471. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10472. Plaintiffs and the Arizona Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 627:
Negligent Storage and Transportation – Arizona

10473. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77

(describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10474. This cause of action is brought by Tangie Sims, individually and on behalf of the Arizona Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10475. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10476. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10477. Under Arizona law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10478. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10479. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic

Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10480. The latent injuries from which Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10481. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10482. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10483. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10484. Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Arizona Strides Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10485. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Arizona Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10486. Plaintiffs and the Arizona Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Arizona Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. California

COUNT 628:
Negligence – Failure to Warn Through Proper Expiration Dates – California

10487. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10488. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10489. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10490. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10491. Under California law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10492. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10493. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10494. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10495. The latent injuries from which Plaintiffs and the California Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10496. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10497. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10498. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10499. Plaintiffs and the California Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10500. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10501. Plaintiffs and the California Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 629:
Strict Products Liability – Failure to Warn Consumers Through the FDA – California

10502. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10503. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10504. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10505. Plaintiffs incorporate herein by reference Paragraphs 907-36 (Additional Count-Specific Allegations) as to Defendant.

10506. Under California law, manufacturers, including Defendant, bear "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer," which includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers," pursuant to *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429, *as modified* (Feb. 3, 2014).

10507. This duty to warn, owed by Defendant, is ultimately owed to the consumer, not the FDA. Yet, where warning an end consumer or her doctor directly is difficult, manufacturers may fulfill their state law duty to warn by informing the FDA, which is a third party that is reasonably expected to pool and share safety-related information and publicize risks to the medical community.

10508. The FDA was reasonably expected to disseminate this information. No speculation is necessary on this point, because the FDA in fact did warn consumers and the medical community

when they learned of these risks.

10509. Because federal law requires generic drug labels to largely match branded drug labels, *see* 21 C.F.R. § 314.94(a), Defendant was not able to warn consumers directly of the cancer risks of NDMA in ranitidine. Rather than warning the FDA as a third party who would disseminate information to the public, Defendant failed to warn anyone through any medium.

10510. Specifically, Defendant failed to submit adverse event reports related to cancer for ranitidine, as required by FDA regulations. Defendant also failed to warn the FDA of the risks that ranitidine degrades into NDMA and causes cancer through other communication channels that were available, including ordinary correspondence with the agency or regulatory reporting.

10511. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the California Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10512. The latent injuries from which Plaintiffs and the California Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10513. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

10514. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10515. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10516. Plaintiffs and the California Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10517. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10518. Plaintiffs and the California Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 630:
Negligent Product Containers – California

10519. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10520. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10521. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10522. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10523. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10524. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10525. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the California Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10526. The latent injuries from which Plaintiffs and the California Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10527. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10528. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10529. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10530. Plaintiffs and the California Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10531. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10532. Plaintiffs and the California Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 631:
Negligent Storage and Transportation – California

10533. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the

breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10534. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the California Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10535. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10536. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10537. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10538. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10539. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the California Strides Equate Medical Monitoring Class members have sustained a significantly

increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10540. The latent injuries from which Plaintiffs and the California Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10541. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10542. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10543. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10544. Plaintiffs and the California Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California Strides Equate Medical

Monitoring Class members as frequently and appropriately as necessary.

10545. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10546. Plaintiffs and the California Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Colorado

COUNT 632:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Colorado

10547. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to

warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10548. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10549. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10550. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10551. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10552. Under Colorado law, a manufacturer, including Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

10553. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10554. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10555. As a direct and proximate result of Defendant's failure to provide an adequate

warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10556. The latent injuries from which Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10557. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10558. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10559. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10560. Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Strides Equate Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10561. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10562. Plaintiffs and the Colorado Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 633:
Medical Monitoring – Negligent Product Containers – Colorado

10563. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory

framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10564. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10565. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10566. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10567. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10568. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10569. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10570. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10571. The latent injuries from which Plaintiffs and the Colorado Strides Equate Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10572. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10573. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10574. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10575. Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10576. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10577. Plaintiffs and the Colorado Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 634:
Medical Monitoring – Negligent Storage and Transportation – Colorado

10578. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10579. This cause of action is brought by Jeffrey Pisano and Ronald Ragan, individually and on behalf of the Colorado Strides Equate Medical Monitoring Class (for the purposes of this

Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10580. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10581. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10582. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10583. Under Colorado law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10584. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10585. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10586. The latent injuries from which Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10587. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10588. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10589. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10590. Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10591. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado Strides Equate Medical Monitoring Class members in writing that they may

require frequent medical monitoring for the purpose of diagnosis.

Plaintiffs and the Colorado Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Florida

COUNT 635:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – Florida

10592. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10593. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10594. The allegations in this Count apply to Strides during the time period in which it was

manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10595. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10596. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10597. Under Florida law, pharmaceutical manufacturers, including Defendant, have a duty of reasonable care to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

10598. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10599. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10600. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the Florida Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10601. The latent injuries from which Plaintiffs and the Florida Strides Equate Medical

Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10602. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10603. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10604. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10605. Plaintiffs and the Florida Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10606. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10607. Plaintiffs and the Florida Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 636:
Medical Monitoring – Negligent Product Containers – Florida

10608. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10609. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Strides Equate Medical Monitoring Class (for the purposes of this Count,

"Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10610. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10611. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10612. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10613. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10614. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10615. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the Florida Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10616. The latent injuries from which Plaintiffs and the Florida Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10617. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10618. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10619. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10620. Plaintiffs and the Florida Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10621. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10622. Plaintiffs and the Florida Strides Equate Medical Monitoring Class have an

inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 637:
Medical Monitoring – Negligent Storage and Transportation – Florida

10623. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10624. This cause of action is brought by Michael Tomlinson, individually and on behalf of the Florida Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10625. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10626. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-

Specific Allegations) as to Defendant.

10627. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10628. Under Florida law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10629. Defendant breached this duty by failing to implement or enforce policies to ensure its Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10630. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the Florida Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10631. The latent injuries from which Plaintiffs and the Florida Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10632. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the

development of, and health effects associated with, the Subject Cancers.

10633. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10634. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10635. Plaintiffs and the Florida Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10636. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10637. Plaintiffs and the Florida Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Florida Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. West Virginia

COUNT 638:
Medical Monitoring – Failure to Warn Through Proper Expiration Dates – West Virginia

10638. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10639. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10640. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10641. Plaintiffs incorporate herein by reference Paragraphs 880-906 (Additional Count-Specific Allegations) as to Defendant.

10642. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased

their risk of developing serious and potentially fatal Subject Cancers.

10643. Under West Virginia law, a manufacturer, including Defendant, has the duty to provide an adequate warning of the risks of its products if it is reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning.

10644. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

10645. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

10646. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of its Ranitidine-Containing Products, Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10647. The latent injuries from which Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10648. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10649. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10650. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10651. Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10652. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10653. Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of

long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 639:
Medical Monitoring – Negligent Product Containers – West Virginia

10654. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10655. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10656. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10657. Plaintiffs incorporate herein by reference Paragraphs 937-50 (Additional Count-Specific Allegations) as to Defendant.

10658. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10659. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

10660. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

10661. As a direct and proximate result of this failure, excessive levels of NDMA built up in Defendant's Ranitidine-Containing Products, and therefore Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10662. The latent injuries from which Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10663. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10664. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and

treatment of the Subject Cancers.

10665. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10666. Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10667. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10668. Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 640:
Medical Monitoring – Negligent Storage and Transportation – West Virginia

10669. Plaintiffs incorporate by reference each allegation set forth in paragraphs 25-77 (describing Generic Prescription Manufacturer Defendants), 318-23 (describing the regulatory framework for generics), 185-249 (describing the recall of ranitidine), 254-91 (describing the breakdown of ranitidine after ingestion), 292-304 (describing the breakdown of ranitidine before ingestion), 305-16 (describing Defendant's knowledge), 324-31 (describing failure to notify FDA), 332-59 (describing good manufacturing practices), 409–31 (describing the regulatory framework for drug manufacturers), 631-56 (describing Store-Brand Manufacturers' failure to warn), 796-840 (describing Strides-specific allegations), and 975-85 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

10670. This cause of action is brought by Mynetta Hastings, individually and on behalf of the West Virginia Strides Equate Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against Strides (for the purposes of this Count, "Defendant").

10671. The allegations in this Count apply to Strides during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 172-84, which are incorporated by reference.

10672. Plaintiffs incorporate herein by reference Paragraphs 951-74 (Additional Count-Specific Allegations) as to Defendant.

10673. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

10674. Under West Virginia law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

10675. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

10676. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products each Brand-Name and Generic Manufacturer Defendant manufactured, stored, and transported, and therefore Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10677. The latent injuries from which Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

10678. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

10679. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

10680. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the West Virginia

Strides Equate Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

10681. Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members seek creation of a Court-supervised, defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members as frequently and appropriately as necessary.

10682. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all West Virginia Strides Equate Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

10683. Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the West Virginia Strides Equate Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

X. PRAYER FOR RELIEF

Plaintiffs, on behalf of themselves and the proposed State Classes, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4), direct that reasonable notice of this action be given to the State Classes, appoint Plaintiffs as named representatives of their respective State Classes, and appoint Plaintiffs' counsel as Class Counsel;

B. Enter judgment against Defendants and in favor of Plaintiffs and the State Classes;

C. Grant equitable relief in the form of a medical monitoring program to be funded by Defendants;

D. Award Plaintiffs and the State Classes their costs of suit, including reasonable attorneys' fees, as provided by law;

E. Award any other relief that is deemed just and proper.

XI. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the State Classes, demand a trial by jury on all issues to triable.

DATED: February 22, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/ Robert C. Gilbert
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