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 CONSUMER CLASS ACTION COMPLAINT

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Plaintiffs bring this consolidated class action on behalf of themselves and all others similarly situated against the defendants named herein (collectively, "Defendants") and seek damages and equitable relief to remedy the harms caused by Defendants' unlawful design, 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"). Based upon personal knowledge as to Plaintiffs' own conduct, and upon information and belief, including through investigation of counsel, as to all other matters, Plaintiffs allege as follows:

INTRODUCTION

1. From 1983 until 2020 when Ranitidine-Containing Products were pulled from shelves following the U.S. Food & Drug Administration's ("FDA") confirmation of "unacceptable levels" of a known carcinogen, Defendants made billions of dollars by uniformly deceiving millions of consumers into purchasing and ingesting a defective, misbranded, adulterated, and harmful drug that would not have been available for sale in the U.S., and that consumers would not have purchased nor ingested, but for Defendants' unlawful conduct alleged herein. Through their actions, omissions, and failures in the design, manufacture, marketing, packaging, labeling, handling, distribution, storage, and/or sale of Ranitidine-Containing Products, each Defendant in the pharmaceutical supply chain violated federal law and/or state law, as detailed below. As a direct and proximate result of Defendants' unlawful conduct alleged herein, consumers, including Plaintiffs and the Class (defined below), suffered economic losses and now face an increased risk of developing cancer, which will require them to endure costly medical monitoring, treatments, and/or medications for the rest of their lives, and to live with the fear of developing cancer.

2. Zantac was one of the most widely prescribed and OTC heartburn and indigestion medications on the market. It was the first-ever "blockbuster" drug to reach $1 billion in sales. Zantac's unprecedented sales were made possible only because of a deceptive and unlawful scheme to defraud consumers regarding the purported safety of Ranitidine-Containing Products and to conceal from consumers the known dangers and risks associated with the use of these products.

3. As alleged herein, the Brand-Name Manufacturer Defendants (defined below) engaged in a national, pervasive, and decades-long campaign of uniform misrepresentations and omissions designed to conceal the inherent dangers and risks associated with ranitidine use and to mislead consumers into believing that Zantac was safe for human consumption. Through product labels and packaging; print, TV, radio, and online advertising; Internet websites; and social media, the Brand-Name Manufacturer Defendants uniformly represented to consumers and health professionals that Zantac was safe, *e.g.*, so safe that it could be used frequently, for chronic conditions, and for fast relief with nitrite- and nitrate-rich foods (*i.e.* foods that induce heartburn).

4. These representations were false, deceptive, and misleading when made, and they omitted material facts known to Defendants regarding the true risks of Ranitidine-Containing Products. Contrary to the Brand-Name Manufacturer Defendants' misrepresentations, ranitidine is a dangerous chemical that is unsafe and unfit for human consumption. The ranitidine molecule itself is unstable and – under ***normal*** conditions – degrades into high levels of N-

Nitrosodimethylamine ("NDMA"), a chemical the World Health Organization ("WHO") has described as "***clearly carcinogenic***."[1]

5. NDMA was discovered through the manufacture of rocket fuel. Its only use today is to cause cancer in laboratory animals. While any exposure to NDMA can be harmful, the FDA has set the ***maximum*** allowable daily limit of NDMA to 96 nanograms (ng). For reference, one filtered cigarette contains between 5 to 43 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 once nightly for 4 to 8 weeks, and maintenance doses of 150 mg once daily."[2] Thus, consumers of Ranitidine-Containing Products have likely been exposed to staggering levels of carcinogenic NDMA during the relevant period.

6. The breakdown of the ranitidine molecule into NDMA under normal conditions is exacerbated in the environment of the human stomach and other organs. The presence of nitrite- and nitrate-rich foods, *i.e.*, heartburn-inducing foods, exacerbates the breakdown process even further. Thus, contrary to the Brand-Name Manufacturer Defendants' misrepresentations, Zantac was not safe for human consumption.

7. The NDMA levels resulting from the breakdown of the unstable ranitidine molecule under normal conditions, as well as when combined with gastric fluid and nitrite- and nitrate-rich foods, are sufficiently high to expose consumers to unreasonable and unacceptable health risks.

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[1] 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.

[2] *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/.

To make matters worse, however, the breakdown process of ranitidine into NDMA is accelerated and/or exacerbated by exposure to normal levels of heat found during the manufacturing, transportation, and/or storage processes. Each Defendant in the pharmaceutical supply chain failed to: (a) comply with Current Good Manufacturing Practices ("cGMPs") to ensure their products met safety, quality, purity, identity, and strength standards; (b) conduct stability testing of their Ranitidine-Containing Products to assess the stability characteristics of those products and ensure bioequivalence; (c) take necessary steps to ensure proper manufacture, transportation, handling, and storage of their Ranitidine-Containing Products so as to avoid exposure to heat; and (d) to disclose these material facts to consumers.

8. Defendants knew or should have known that ranitidine is an unstable molecule that breaks down under normal conditions into dangerous NDMA, and that this breakdown process is made worse when ranitidine is used in the directed manner or when it is exposed to heat. Indeed, in 1981 – ***two years before Zantac hit the market*** – Dr. Silvio de Flora published the results of experiments exposing ranitidine to human gastric fluid in combination with nitrites, which showed "toxic and mutagenic effects[.]"[3] As a result, Dr. de Flora cautioned that "***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[.]***" *Id.*

9. Brand-Name Manufacturer Defendant GSK (as defined herein), the originator of the ranitidine molecule, had actual knowledge of this study. Rather than investigate the concerns raised in Dr. de Flora's study to ensure its product was safe and not harmful to users, GSK attempted to discredit the study. Two weeks after its publication, GSK responded to Dr. de Flora's

[3] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, 318 LANCET 8253, 993-94 (Oct. 31, 1981).

findings, claiming that the levels of nitrite needed to induce the production of NDMA were unrealistic and not likely to be experienced in the real world and, thus, the results had no "practical clinical significance."[4] Numerous other studies raised concerns over ranitidine and cancerous nitroso compounds. GSK attempted to parry these studies with its own studies that were clearly rigged in order to avoid reaching the same undeniable conclusion: ranitidine breaks down into carcinogenic NDMA when used in the manner Defendants directed. In the study that was presented to the FDA for approval of Zantac, however, GSK admitted that ranitidine could convert into NDMA and cause cancer, but GSK dismissed this risk because Ranitidine-Containing Products were purportedly intended to be used for a short-term period. These material facts were known, or should have been known, by each Defendant, which was duty-bound to investigate the potential dangers and risks associated Ranitidine-Containing Products and to ensure that such products were safe for human consumption.

10. Despite Defendants' knowledge of these material facts regarding the dangers and risks associated with the use of Ranitidine-Containing Products, which were well known and widely available to the scientific community but not the public, Defendants did not disclose to consumers, including Plaintiffs and the Class, that their Ranitidine-Containing Products were unsafe, that the ranitidine molecule breaks down into carcinogenic NDMA at levels that exceed the maximum daily limit, that ranitidine should not be used for long-term periods, or that ranitidine should not be consumed with nitrite- and nitrate-rich foods. To the contrary, Defendants made affirmative misrepresentations to Plaintiffs and the Class regarding each of these material facts

[4] 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.

and the safety of ranitidine in general, which further created a duty for Defendants to disclose these material facts.

11. In 2019, Valisure LLC and ValisureRX LLC ("Valisure"), 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, Valisure filed a citizen petition with the FDA asking the agency to recall all products that contain ranitidine. Valisure provided copies of the petition to the WHO and International Agency for the Research of Cancer ("IARC"). Less than a month later, in early October 2019, the FDA ordered testing on Ranitidine-Containing Products and specified the protocols for such testing. Within days of the FDA's announcement, certain Brand-Manufacturing Defendants recalled all their 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 Ranitidine-Containing Products and requested that all manufacturers recall their Ranitidine-Containing Products. Ultimately, on April 1, 2020, the FDA called for a withdrawal of all Ranitidine-Containing Products in the United States, citing unacceptable levels of NDMA in those drugs.

12. By designing, manufacturing, distributing, packaging, labeling, marketing, and/or selling Ranitidine-Containing Products without adequate testing or labels and warnings; failing to ensure the proper conditions for the manufacture, transportation, handling, and storage of Ranitidine-Containing Products; and misrepresenting and not disclosing material facts regarding the safety of Ranitidine-Containing Products and the dangers and risks associated with their intended use, Defendants violated federal and/or state law and common law, as alleged herein.

13. As a direct and proximate result of Defendants' violations of law, Plaintiffs and other members of the Class have suffered economic losses through their purchase of a product that should not have been available for sale in the U.S. and which they would not have purchased, but for Defendants' unlawful conduct. As a direct and proximate result of Defendants' violations of law, Plaintiffs and other members of the Class who ingested Ranitidine-Containing Products face an increased risk of developing cancer and will be forced to pay for and endure lifelong medical monitoring, treatments, and/or medications, and to live with the fear and risk of developing additional health consequences, such as cancer.

14. As detailed below, Plaintiffs, individually and on behalf of the Class assert, claims for violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1962(c)-(d), the Magnuson-Moss Warranty Act ("MMWA"), 15 U.S.C. §2301, *et seq.*, and state consumer protection laws; breach of implied and express warranties; fraud; negligence; strict liability for design defects, manufacturing defects, and failure to warn; battery; and unjust enrichment.

15. As detailed below, Plaintiffs, individually and on behalf of the Class, seek redress to compensate for their economic losses, to provide for the medical monitoring they require, and to deter the type of misconduct that caused to the damages suffered by Plaintiffs and the Class.

JURISDICTION AND VENUE

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

PARTIES

I. PLAINTIFFS

21. Plaintiff Anthony McGhee (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac and ranitidine syrup and Zantac tablets and capsules, from approximately 2013 to 2020 to treat allergies, from CVS and a U.S. Department of Veterans Affairs ("VA") hospital in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

22. Plaintiff Daffeney Austin (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2016 to 2019 to treat acid reflux, from Walmart

in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

23. Plaintiff Dennis Hall (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2004 to 2016 to treat acid reflux and gastroesophageal reflux disease ("GERD"), from a Rite Aid, Dalton Pharmacy, Mike's Pharmacy, Family Dollar, Winn-Dixie, and Dollar General in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

24. Plaintiff Gentrell Eatman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules, from approximately 2013 to 2017 to treat severe heartburn, from a Walgreens, CVS, and Publix in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

25. Plaintiff Jeremy Hilton (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1995 to 2012 to treat acid reflux, from a Walmart, Hokes Bluff Pharmacy, Hugh's Pharmacy, Physician's Apothecary, Ballplay Grocery, and Dollar General in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion

of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

26. Plaintiff Lashonnah Gaitor (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Ranitidine tablets and capsules, from approximately 2015 to 2016 to treat acid reflux and heartburn, from a Walgreens in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

27. Plaintiff Linda Burns (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2020 to treat indigestion, stomach bloating and acid reflux, from Walmart

and Lake Martin Pharmacy in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

28. Plaintiff Sally Jackson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alabama. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2008 to 2019 to treat acid reflux and heartburn, from a Dollar General and Walmart in Alabama. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

29. Plaintiff Tammy Smith (for the purpose of this paragraph, "Plaintiff"), is a citizen of Alaska. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1989 to 2019 to treat ulcers, GERD, heartburn, and indigestion, from a Safeway pharmacy in Alaska; military base commissaries in Texas, Louisiana, Missouri, and Alaska; and a Walmart in Arizona. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

30. Plaintiff Armando Tapia (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arizona. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules, Zantac injection, ranitidine tablets and capsules, from approximately 2007 to 2019 to treat severe acid reflux, from Mariposa Community Pharmacy and Food City Pharmacy in Arizona. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac tablets, capsules, and injections had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

31. Plaintiff Juan Montanez (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arizona. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules, from approximately 2013 to 2020 to treat heartburn and acid-reflux from a Safeway or Sam's Club in Arizona. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

32. Plaintiff Monica Costello (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arizona. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2018 to treat stomach issues, from a CVS in Arizona. As a direct and proximate result of Defendants'

breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

33. Plaintiff Tangie Sims (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arizona. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2007 to 2020 to treat heartburn, from a Walgreens, Walmart, Safeway, and Fry's Grocery Store in Arizona. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

34. Plaintiff Andy Green (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arkansas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and prescription ranitidine tablets and capsules, from approximately 1980 to 2019 to treat acid reflux, from a Walgreens and Walmart in Arkansas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

35. Plaintiff Tina Culclager (for the purpose of this paragraph, "Plaintiff"), is a citizen of Arkansas. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules, from approximately 2015 to 2019 to treat acid reflux, from a Walmart and Walgreens in Arkansas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied

warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

36. Plaintiff Cesar Machado (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules from approximately 2016 to 2020, to treat gastritis, from Costco in California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

37. Plaintiff Golbenaz Bakhtiar (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2000 to 2019 to treat acid reflux and GERD, from Albertson's, Walgreens, Ralph's, and Target in California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

38. Plaintiff Kang Lim (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules from approximately 2005 to 2019, to treat gastritis from Kaiser, Walgreens, and CVS in California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

39. Plaintiff Lynette Newton (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2005 to 2019, to treat severe heartburn, from a Kaiser Permanente, and Rite Aid in

California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

40. Plaintiff Richard Obrien (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1998 to 2019, to treat gastrointestinal problems, from a CVS and Rite Aid in California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

41. Plaintiff Royal Handy (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Ranitidine tablets and capsules, from approximately 2015 to 2019 to treat acid reflux and GERD, from a CVS in California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

42. Plaintiff Virginia Aragon (for the purpose of this paragraph, "Plaintiff"), is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2006 to 2020 to treat heartburn, from a Kaiser, Walmart, and CVS in California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and

implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

43. Plaintiff Ronald Ragan (for the purpose of this paragraph, "Plaintiff"), is a citizen of Colorado. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2012 to 2019 to treat acid reflux and heartburn from a Walmart in Colorado. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

44. Plaintiff Jeffrey Pisano (for the purpose of this paragraph, "Plaintiff"), is a citizen of Colorado. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1998 to 2020 to treat heartburn, from a Safeway, Walgreens, Walmart, Osco Drug, and Rite Aid in Colorado. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage,

distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

45. Plaintiff Angel Cordero (for the purpose of this paragraph, "Plaintiff"), is a citizen of Connecticut. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2007 to 2019 to treat a sensitive stomach and acid buildup, from a CVS and local convenience stores in Connecticut. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

46. Plaintiff Eva Swint (for the purpose of this paragraph, "Plaintiff"), is a citizen of Delaware. Plaintiff purchased and used Ranitidine-Containing Products, including prescription

Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2016 to 2019 to treat allergy problems and stomach issues, from a VA in Delaware. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

47. Plaintiff Jennifer Marks (for the purpose of this paragraph, "Plaintiff"), is a citizen of Delaware. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules, from approximately 2014 to 2019 to treat reflux and heartburn, from a Rite Aid and Walmart in Delaware. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks

associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

48. 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, including prescription ranitidine tablets and capsules, in 2018 to treat acid reflux, from a Med LLC Pharmacy in Maryland. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

49. Plaintiff Ana Pereira (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2020 to treat acid reflux, from American Health Care in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels

of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

50. Plaintiff Clifton McKinnon (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2008 to 2020 to treat acid reflux, from Walgreens in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

51. Plaintiff Daniel Taylor (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2015 to 2020 to treat stomach pain and acid reflux, from a CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and

negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

52. Plaintiff Digna Arbizu (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2019 to 2020 to treat stomach pain and acid reflux, from CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

53. Plaintiff Gustavo Velasquez (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC

Zantac tablets and capsules, from approximately 2000 to 2020 to treat acid reflux, from CVS, Walgreens, and Publix in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

54. Plaintiff Hattie Kelley (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2014 to 2018 to treat GERD, from a Walgreens in Florida, and a CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

55. Plaintiff Irma Arcaya (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2014 to 2020 to treat acid reflux, from a Suncoast Community Health Centers, Inc. and CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

56. Plaintiff Jeffrey Beauchamps (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2010 to 2018 to treat acid reflux, from a CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels

of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

57. Plaintiff Jeannie Black (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2015 to 2020 to treat acid reflux and heart burn, from a Walgreens in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

58. Plaintiff John Wholey (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac and ranitidine tablets and capsules, and prescription ranitidine (injection), from approximately 1990 to 2019 to treat ulcers from 7-Eleven, Walgreens, and various convenience stores in Massachusetts and from CVS and a hospital in Florida. As a direct and proximate result of Defendants' breaches

of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac tablets, capsules, and ranitidine injections had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

59. Plaintiff Jose Alfredo Contreras (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules from approximately 2012 to 2017 to treat with acid reflux, from a CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

60. Plaintiff Joshua Winans (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2000 to 2020 to treat GERD, from CVS, Walgreens, Walmart, Sam's Club, and Publix in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

61. Plaintiff Joyce Taylor (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2020 to treat heart burn, from multiple CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted,

concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

62. 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, including prescription ranitidine syrup, from approximately 1999 to 2020 to treat acid reflux, from Nemours Children's Hospital pharmacy, CVS, and Walgreens in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

63. Plaintiff Kristen Monger, as legal guardian 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, including prescription ranitidine syrup, from approximately 1997 to 2020 to treat acid reflux, from a Nemours Children's Hospital pharmacy, CVS, Walgreens in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in

connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products, including prescription ranitidine syrup had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

64. Plaintiff Louise Brooks (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2019 to treat acid reflux, from Orange Blossom Family Health in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

65. Plaintiff Manuel Rodriguez (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including

prescription ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2007 to 2019 to treat stomach pains, from a Walgreens and CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

66. Plaintiff Maria De Oliveira (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2020 to treat heartburn, from Walmart in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks

associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

67. Plaintiff Maria Tate (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1995 to 2015 to treat acid reflux and peptic ulcer disease, from Walmart RX Plus (Advent Health Hematology and Oncology), and Sam's Club in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

68. Plaintiff Marva McCall (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2007 to 2019 to treat acid reflux and heartburn, from a CVS and Walgreens in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion

of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

69. Plaintiff Michael Fesser (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2019 to treat heartburn, acid reflux, and gout from a Walmart in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

70. Plaintiff Michael Tomlinson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and prescription ranitidine tablets and capsules, from approximately 2004 to 2019 to treat acid reflux, from a VA pharmacy and Walmart in Florida. As a direct and

proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

71. Plaintiff Moises Egozi (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 1980 to 2019 to treat an upset stomach, from Walgreens and CVS in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

72. Plaintiff Robert Nash (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2004 to 2020 to treat severe heartburn, from gas stations, Dollar General, and Walmart in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

73. Plaintiff Ricardo Moròn (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 1995 to 2020 to treat heartburn and acid reflux, from Publix and Walmart in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted,

concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

74. Plaintiff Roy Armstrong (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules ranitidine tablets and capsules, from approximately 2006 to 2019 to treat acid reflux and GERD, from Walgreens and CVS in Georgia, and Walgreens in Michigan and Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

75. Plaintiff Sharon Tweg (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules, from approximately 2010 to 2019 to treat heartburn and stomach-related issues, from a Walgreens, CVS, and Publix in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their

development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

76. Plaintiff Sonia Diaz (for the purpose of this paragraph, "Plaintiff"), is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2004 to 2020 to treat acid reflux and bloating, from La Farmacia Gabriela in Puerto Rico and Winter Garden Pharmacy in Florida. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

77. Plaintiff Angela Taylor (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription

ranitidine tablets and capsules, from approximately 2006 to 2020 to treat acid reflux, heartburn and stomach ulcer, from Walgreens in Tennessee, and Walgreens and Publix in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

78. Plaintiff Charlotte Sanders (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2014 to 2020 to treat esophagitis and heartburn, from CVS in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

79. Plaintiff Cynthia Starr (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2020 to treat heartburn, from a Publix in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

80. Plaintiff Earlene Green (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including both OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1995 to 2020 to treat acid reflux, heartburn, and GERD, from Walmart in Georgia and Walgreens in Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

81. Plaintiff Kathy Jeffries (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1998 to 2019 to treat heartburn, stomach acid and esophagus acid, from CVS, Kroger and Family Dollar in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

82. Plaintiff Leon Greene (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2016 to 2020

to treat stomach problems and heartburn, from a Walmart in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

83. Plaintiff Paula Shells (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2016 to 2019 to treat acid reflux and irritable bowel syndrome, from CVS in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

84. Plaintiff Sandra Brackins (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2019 to treat acid reflux and indigestion from Harvey's Pharmacy and Walmart in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

85. Plaintiff Tyrone Houston (for the purpose of this paragraph, "Plaintiff"), is a citizen of Georgia. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, until approximately 2020 to treat heartburn and acid reflux, from a Kroger's in Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and

implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

86. Plaintiff Carol Harkins (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2005 to 2020 to treat heartburn, from a Walmart, Walgreens, Kroger, Sam's Club, and Costco in Illinois. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

87. Plaintiff David Simpson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets, capsules, and syrup, and OTC Zantac tablets and capsules, from approximately 2003 to 2020 to treat gastrointestinal bleeding, from CVS and Walgreens in Illinois. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and

promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

88. Plaintiff Denise Guy (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules from approximately 2015 to 2020 to treat heartburn, from Walgreens, Family Dollar, and Dollar General in Illinois. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

89. Plaintiff Heather Re (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2013 to 2020 to treat acid reflux, from CVS, Walgreens, and Sullivan's Pharmacy in Illinois. As

a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

90. Plaintiff Jacqueline Hanson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2008 to 2020 to treat heartburn and acid reflux, from Walgreens and CVS in Illinois and Walgreens and CVS in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

91. Plaintiff Renee Chatman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules, from approximately 2010 to 2019 in Illinois. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

92. Plaintiff Shannon Williams (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2015 to 2019 to treat GERD from Walgreens and Walmart in Illinois. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

93. Plaintiff Vickie Anderson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Illinois. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2012 to 2020 to treat ulcers and acid reflux, from Walmart and Walgreens located in Illinois. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

94. Plaintiff Alyson Humphrey (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2020 to treat nausea and upper-related pain, from a Kroger, Dollar General, and Dollar Tree in Indiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

95. Plaintiff Brenda Henderson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2019 to treat heartburn and GERD, from Walmart in Indiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

96. Plaintiff Carol Grimes (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2019 to treat ulcers, from Walmart in Indiana. As a direct and proximate result of Defendants'

breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

97. Plaintiff Rebecca Sizemore (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2015 to 2020 to treat stomach problems such as acid reflux, gastritis, and diverticulitis, from CVS in Indiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

98. Plaintiff Teresa Dowler (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2019 to treat GERD symptoms and an ulcer in her esophagus, from CVS in Indiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

99. Plaintiff Timberly Goble (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2013 to 2020 to treat acid reflux and heartburn, from Walmart in Missouri and Kentucky, Walgreens in Indiana, and online delivery from ExactCare. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels

of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

100. Plaintiff Tracy Wells (for the purpose of this paragraph, "Plaintiff"), is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2013 to 2020 to treat acid reflux, from Walmart and CVS in Indiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

101. Plaintiff Brian Nervig (for the purpose of this paragraph, "Plaintiff") is a citizen of Iowa. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2020 to treat an ulcer, from Hy-Vee, Dollar General, and Walgreens in Iowa. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts,

fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

102. Plaintiff Tracy Losee (for the purpose of this paragraph, "Plaintiff"), is a citizen of Iowa. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2017 to 2020 to treat acid reflux, from Walgreens and Express Scripts in Iowa. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

103. Plaintiff Darla Curtis (for the purpose of this paragraph, "Plaintiff"), is a citizen of Kentucky. Plaintiff purchased and used Ranitidine-Containing Products, including both

prescription and OTC Zantac tablets and capsules, from approximately the mid-1990s to 2018 to treat acid reflux and heartburn, from Bluegrass Pharmacy, Walgreens, CVS, Rite Aid, and Walmart in Kentucky. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

104. Plaintiff Janet Asbury (for the purpose of this paragraph, "Plaintiff"), is a citizen of Kentucky. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1991 to 1996 to treat heartburn and acid, from a Kmart and Rite Aid in Kentucky. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the

risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

105. Plaintiff Judy Clark (for the purpose of this paragraph, "Plaintiff"), is a citizen of Kentucky. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2019 to treat heartburn and acid reflux, from Kroger and Walmart in Kentucky. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

106. Plaintiff Jamie McKay (for the purpose of this paragraph, "Plaintiff"), is a citizen of Louisiana. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2018 to 2019 to treat heartburn and indigestion, from Walmart and Dollar Store in Louisiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion

of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

107. Plaintiff Randy Jones (for the purpose of this paragraph, "Plaintiff") is a citizen of Louisiana. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac and ranitidine tablets and capsules and ranitidine tablets and capsules, from approximately 2002 to 2020 to treat acid reflux, from Humana mail order and JenCare Senior Medical Center and Walmart in Louisiana. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

108. Plaintiff Bobbi Marshall (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maine. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2019 to treat GERD and gastroparesis,

from a Holland's Variety Drug in Maine. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate 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, including prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2000 to March 2020 to treat acid reflux from Walgreens, CVS, Rite-Aid, and Homecare Delivery in Maryland. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

110. Plaintiff Darlene Whittington-Coates (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2017 to 2019 to treat digestive and esophageal discomfort, from Annapolis Medical Center in Maryland. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used ranitidine tablets and capsules had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

111. Plaintiff Ida Adams (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2010 to 2017 to treat heartburn, from Walmart in Maryland. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels

of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

112. Plaintiff Kelly Spillman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1994 to 2020 to treat acid reflux , from CVS and Walgreens in Maryland, as well as in Delaware. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

113. Plaintiff Ana Guzman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Massachusetts. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2015 to 2020 to treat stomach pains and acid reflux, from Walgreens in Massachusetts. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent

misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used ranitidine tablets and capsules had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

114. Plaintiff Jennifer Bond (for the purpose of this paragraph, "Plaintiff"), is a citizen of Massachusetts. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules, from CVS from approximately 2010 to 2019 in Massachusetts. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

115. Plaintiff Jose Amado (for the purpose of this paragraph, "Plaintiff"), is a citizen of Massachusetts. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from

approximately 2015 to 2018 to treat stomach aches, acid reflux, and heartburn, from a RiteAid and Walgreens in Massachusetts. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

116. Plaintiff Kirenia Alvarez (for the purpose of this paragraph, "Plaintiff"), is a citizen of Massachusetts. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules from approximately 2016 to 2020 to treat nausea and acid reflux, from CVS, Walmart, and Rite Aid in Massachusetts. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

117. Plaintiff Michelle Smith (for the purpose of this paragraph, "Plaintiff"), is a citizen of Massachusetts. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2015 to 2020 to treat acid reflux and heartburn, from CVS in Massachusetts. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

118. Plaintiff Arthur Gamble (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2017 to 2018 to treat excessive burping and gas, from Kroger and CVS in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-

Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

119. Plaintiff Benny Cope (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2016 to 2019 to treat acid reflux and heartburn, from an Action Drugs Michigan; and Malek Pharmacy in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

120. Plaintiff Jerry Hunt (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1989 to 2019 to treat constant heartburn, from Walgreens, Walmart, Meijer's, and Sam's Club in Michigan. As a direct and proximate result of Defendants' breaches of express and implied

warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

121. Plaintiff Jody Beal (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules, from approximately 2011 to 2009 to treat acid reflux, from Martin's Pharmacy, Walmart, and Walgreens in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

122. Plaintiff Judy Wilmot (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules during several months in 2019 to treat her irritated digestive system, from Meijer's in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

123. Plaintiff Lakisha Wilson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including both Zantac and ranitidine tablets and capsules from approximately 1997 to 2017 to treat acid reflux, GERD, and ulcers from MedCart, Safari Drugs, Knight Drugs, Rx Care, Direct Rx, Rite Aid, CVS, and Sav-Max in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had

Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

124. Plaintiff Myra Allen (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2020 to treat acid reflux from Express Scripts. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

125. Plaintiff Sabina McClure (for the purpose of this paragraph, "Plaintiff"), is a citizen of Michigan. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2019 to treat acid reflux and GERD from Eastborn Pharmacy and CVS in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing,

sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

126. Plaintiff Brad Hoag (for the purpose of this paragraph, "Plaintiff"), is a citizen of Minnesota. Plaintiff purchased and used Ranitidine-Containing Products, including both OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2011 to 2019 to treat heartburn, from a Walgreens and CVS in Minnesota and delivered through Amazon in Minnesota. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

127. Plaintiff Donald Northrup (for the purpose of this paragraph, "Plaintiff"), is a citizen of Minnesota. Plaintiff purchased and used Ranitidine-Containing Products, including

prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2000 to 2019 to treat acid-reflux, from Hennepin County Medical Center and Walmart in Minnesota. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

128. Plaintiff John Scholl (for the purpose of this paragraph, "Plaintiff"), is a citizen of Minnesota. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2005 to 2016 to treat acid reflux, from a Target, Walgreens, and Walmart in Minnesota. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

129. Plaintiff Rodriquze Hampton Sr., both in his personal capacity and as a guardian for Rodriquze Hampton Jr. (for the purpose of this paragraph, "Plaintiff"), is a citizen of Minnesota. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac syrup and ranitidine syrup, from approximately 2008 to 2020 to treat heartburn, from a Walgreens in Minnesota and Tennessee; and Children's Hospital in Minnesota. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

130. Plaintiff Sandra Erickson-Brown (for the purpose of this paragraph, "Plaintiff"), is a citizen of Minnesota. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1980 to 2017 to treat heartburn, from Walgreens and Walmart in Minnesota. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion

of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

131. Plaintiff Beverley Crosby (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2014 to 2020 to treat heartburn, from C&C Drugs and Caleb's Hometown Pharmacy in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

132. Plaintiff Celenta Sims (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2000

to 2020 to treat acid reflux, from Canton Discount Drug Mart and Mississippi Discount Drugs, in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

133. Plaintiff David Weatherly (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2020 to treat acid reflux, from Walmart in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

134. Plaintiff Dorothy King (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2019 to 2020 to treat heartburn and acid reflux from Walgreens in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

135. Plaintiff John Rachal (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2000 to 2019 to treat acid reflux, from Walmart and Walgreens in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels

of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

136. Plaintiff Korcis McMillian (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2013 to 2020 to treat acid reflux and heartburn, from Walgreens and Rite Aid in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

137. Plaintiff Lora Mauffray (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2015 to 2019 to treat heartburn, from Walmart in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts,

fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

138. Plaintiff Martha Summers (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2007 to 2020 to treat acid reflux, from a Harps Pharmacy and Walgreens in Arkansas, and a Walgreens in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

139. Plaintiff Melinda M Johnson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including

prescription ranitidine tablets and capsules, from approximately 2003 to 2019 to treat acid reflux, from Walmart in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

140. Plaintiff Michelle Tinker (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2014 to 2020 to treat GERD, from Humana in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

141. Plaintiff Porter Veolia (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2003 to 2020 to treat acid reflux and heartburn, from Walmart in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

142. Plaintiff Shirley Magee (for the purpose of this paragraph, "Plaintiff"), is a citizen of Mississippi. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, for many years until 2020 to treat bleeding ulcer, from Walmart in Mississippi. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing

Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

143. Plaintiff Antrenise Campbell (for the purpose of this paragraph, "Plaintiff") is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules ranitidine tablets and capsules from approximately 1990 to 2013 to treat heartburn and acid reflux, from Walgreens in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

144. Plaintiff Brenda Newcomb (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules from approximately 2016 to 2020 to treat acid reflux, from Bond's Pharmacy in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and

negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

145. Plaintiff Cynthia Gibbs (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules from approximately 2005 to 2019 to treat acid reflux and heartburn, from Medicine Shoppe and Optum RX (United Healthcare) in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

146. Plaintiff Elaine Aaron (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including prescription

ranitidine tablets and capsules, from approximately 2009 to 2020 to treat acid reflux, from CVS in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

147. Plaintiff Joseph Kellum (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2017 to 2020 to treat acid reflux, from Walmart and the VA in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

148. Plaintiff Lisa Deckard (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2013 to 2019 to treat severe heartburn, from Walmart, Walgreens, and Mid-Town Pharmacy in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

149. Plaintiff Lorie Kendall-Songer (for the purpose of this paragraph, "Plaintiff"), is a citizen of Missouri. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2016 to 2020 to treat acid reflux, purchased from a Walmart and Price Chopper in Missouri. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed

herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

150. Plaintiff Angel Vega (for the purpose of this paragraph, "Plaintiff"), is a citizen of Montana. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2009 to 2017 to treat acid reflex, from Kmart in Montana, and CVS and Walgreens in Connecticut. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

151. Plaintiff Charles Longfield (for the purpose of this paragraph, "Plaintiff"), is a citizen of Nebraska. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and prescription generic ranitidine tablets and capsules from approximately 1994 to 2019 to treat acid reflux, purchased from Walmart in Maryland, Virginia,

and Wyoming and a mail-order pharmacy through the VA hospital while in Iowa. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

152. Plaintiff Gaylord Stauffer (for the purpose of this paragraph, "Plaintiff"), is a citizen of Nebraska. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac and ranitidine tablets and capsules, from approximately 1997 to 2019 to treat heartburn and indigestion, from a Sam's Club in Nebraska and South Carolina and Walmart in Nebraska and Georgia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

153. Plaintiff Cesar Pinon (for the purpose of this paragraph, "Plaintiff"), is a citizen of Nevada. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2009 to 2020 to treat acid reflux, from a Smith's in Nevada. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

154. Plaintiff David Rice (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Hampshire. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2005 to 2020 to treat stomach pains, from a CVS in New Hampshire and CVS Caremark and Express Scripts mail-order pharmacies. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

155. Plaintiff Rafael Bermudez (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Hampshire. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2020 to treat acid reflux, from a CVS in Massachusetts and New Hampshire. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

156. Plaintiff Isabel Barroso (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac and ranitidine tablets and capsules, from approximately 2010 to 2020 to treat

gastritis, from a People's Pharmacy and Parentini's Pharmacy in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

157. Plaintiff James Adamo (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2008 to 2020 to treat gastritis, from a Walmart in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

158. Plaintiff Kenniqua Nolan (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules, from approximately 2010 to 2011 to treat acid reflux, from a CVS in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

159. Plaintiff Lynn White (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 1987 to 2019 to treat acid reflux, from a Millers Pharmacy, Walgreens, and Duane Reade in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had

Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

160. Plaintiff Mary Mcmillan (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2012 to 2019 to treat acid reflux, from a Sheefa Pharmacy, Freedom Pharmacy, CVS, and Dollar General in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

161. Plaintiff Mary Moronski (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2012 to 2019 to treat acid reflux, from a Walmart and Walgreens in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and

omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

162. Plaintiff Sayed Eldomiaty (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Jersey. Plaintiff purchased and used Ranitidine-Containing Products, including both OTC and prescription Zantac tablets and capsules, and ranitidine tablets and capsules, from approximately 2012 to 2020 to treat heartburn, from a Walgreens and Rite Aid in New Jersey. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

163. Plaintiff Carrie Martinez (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Mexico. Plaintiff purchased and used Ranitidine-Containing Products, including

prescription ranitidine tablets and capsules, from approximately 2008 to 2015 to treat heartburn, from a Fairview Pharmacy in New Mexico. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

164. Plaintiff Ernesto Sanchez (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Mexico. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2012 to 2020 to treat acid reflux, from a Walgreens and Walmart in New Mexico. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to

timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

165. Plaintiff George Tapia (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Mexico. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules Zantac tablets and capsules, from approximately 2012 to 2020 to treat acid reflux and ulcer, from a Walmart in New Mexico and Express Scripts mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

166. Plaintiff Inez Mazon (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Mexico. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2019 to treat heartburn, from a Walgreens in New Mexico. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

167. Plaintiff Josefina Griego (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Mexico. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, in 2019 to treat reflux, from a Walmart in New Mexico and Express Scripts mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

168. Plaintiff Phyllis Gallegos (for the purpose of this paragraph, "Plaintiff"), is a citizen of New Mexico. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2020 to treat acid reflux, from a Smith's pharmacy in New Mexico. As a direct and proximate result of Defendants'

breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

169. Plaintiff Aida Carlo (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, in 2019 to treat acid reflux, from Express Scripts mail-order pharmacy while living in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

170. Plaintiff Benny Fazio (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2000 to 2019 to treat acid reflux, from a CVS in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

171. Plaintiff Francis Neary (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2014 to 2019 to treat acid reflux, from a CVS and Rite Aid in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted,

concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

172. Plaintiff Glorimar Rodriguez (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules Zantac tablets and capsules, from approximately 2007 to 2019 to treat stomach pains and burning sensations to the throat, from East Jerome Pharmacy, Fordham Road Pharmacy, a Family Dollar, and a Walgreens in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

173. Plaintiff Joseph McPheter (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2011 to 2019 to treat acid reflux and heartburn, from a CVS, Target, and Rite Aid in New York and CVS Caremark mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent

misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

174. Plaintiff Mary Lou Wagner (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2009 to 2019 to treat acid reflux, from a Rite Aid in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

175. Plaintiff Mary McCullen (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including both

prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1998 to 2020 to treat stomach problems, from an East New York pharmacy, Katz Pharmacy, and Avon Pharmacy in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

176. Plaintiff Migdalia Kinney (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules, from approximately 2012 to 2019 to treat acid reflux and an ulcer, from Oval Pharmacy in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks

associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

177. Plaintiff Nereida Cordero (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2015 to 2018 to treat stomach problems including acid reflux and gastritis, from a CVS in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

178. Plaintiff Phyllis Spuler (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2016 to 2019 to treat acid reflux, from a Rite Aid in New York and Aetna mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff

to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

179. Plaintiff Prisca Bae (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2003 to 2019 to treat reddening of the face, from a CVS, Duane Reade, and Walgreens in New York, Florida, and California. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

180. Plaintiff Richard Froehlich (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2016 to 2019 to treat acid reflux, from Walmart and CVS in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and

negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

181. Plaintiff Silomie Clarke (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2015 to 2020 to treat heartburn and acid reflux, from a Walgreens and SilverRod in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

182. Plaintiff Steven Murdock (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2019 to 2020 to treat heartburn and acid reflux, from a Walgreens in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

183. Plaintiff Yesenia Melillo (for the purpose of this paragraph, "Plaintiff"), is a citizen of New York. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine syrup and Zantac tablets and capsules, from approximately 2018 to 2019 to treat acid reflux, from a Walgreens in New York and NewYork-Presbyterian Brooklyn Methodist Hospital. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac tablets and capsules and ranitidine

syrup had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

184. Plaintiff Acia D'amore (for the purpose of this paragraph, "Plaintiff"), is a citizen of North Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2018 to 2019 to treat acid reflux, from a VA pharmacy in North Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

185. Plaintiff Dennis Robbins (for the purpose of this paragraph, "Plaintiff"), is a citizen of North Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including both OTC and prescription Zantac tablets and capsules, ranitidine tablets and capsules, from approximately 1985 to 2019 to treat heartburn, from a VA pharmacy, Hoods Drugstore, Walmart, and Sam's Club in North Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and

negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

186. Plaintiff Julie Turner (for the purpose of this paragraph, "Plaintiff"), is a citizen of North Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2015 to 2018 to treat heartburn, from a Wilson's Community Health Center Pharmacy in North Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

187. Plaintiff Patricia Frazier (for the purpose of this paragraph, "Plaintiff"), is a citizen of North Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules from approximately 2008 to 2015 to treat acid reflux, from a Rite Aid and CVS in North Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

188. Plaintiff Sharon Parks (for the purpose of this paragraph, "Plaintiff"), is a citizen of North Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules, and Zantac tablets and capsules, from approximately 2016 to 2019 to treat acid reflux and gastroesophageal reflux disease (GERD), from a Walmart in North Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had

Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

189. Plaintiff Teresa Lee (for the purpose of this paragraph, "Plaintiff"), is a citizen of North Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2016 to 2020 to treat acid reflux, from a Walgreens in North Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

190. Plaintiff Chris Troyan (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2002 to 2020 to treat heartburn and acid reflux, from a Kroger, CVS, and Walgreens in Ohio. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design,

manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

191. Plaintiff Janett Tillman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules, from approximately 2015 to 2019 to treat stomach issues, from a Sam's Club and Walmart in Ohio and CVS Caremark mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

192. Plaintiff Michael Galloway (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from

approximately 1989 to 2019 to treat gastric reflux, from Walgreens and Kroger in Ohio. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

193. Plaintiff Patricia Hess (for the purpose of this paragraph, "Plaintiff"), is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2019 to treat indigestion and heartburn, from a CVS, Kroger, and Dollar General in Ohio. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

194. Plaintiff Billy Naab (for the purpose of this paragraph, "Plaintiff"), is a citizen of Oklahoma. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules and Zantac tablets and capsules from approximately 2000 to 2017 to treat heartburn and acid reflux, from Albertson's in Idaho, and Walmart in Oklahoma, Idaho, and Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

195. Plaintiff Demarco Grayson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Oklahoma. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules from approximately 2011 to 2020 to treat heartburn, from Walgreens, QuikTrip, and the Indian Healthcare Resource Center of Tulsa in Oklahoma. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing

Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

196. Plaintiff Kristi Ledbetter (for the purpose of this paragraph, "Plaintiff"), is a citizen of Oregon. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC ranitidine tablets and capsules, from approximately 2013 to 2016 to treat heartburn, from a Walgreens and Ray's Food Place in Oregon. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

197. Plaintiff Carol Loggins (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine syrup, from approximately 2013 to 2020 to treat esophagitis, from a CVS in Pennsylvania. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in

connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

198. Plaintiff Elmer Cook (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2019 to 2020 to treat severe heartburn, from a VA pharmacy in Pennsylvania. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

199. Plaintiff Felicia Ball (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products, including

prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2000 to 2020, to treat irritable bowel syndrome (IBS), from a Giant Eagle Pharmacy in Pennsylvania. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

200. Plaintiff Joyce Guerrieri (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules from approximately 2009 to 2019 to treat acid reflux from a Rite Aid in New York. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

201. Plaintiff Nicholas Hazlett (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine syrup and Zantac and ranitidine tablets and capsules, from approximately 2005 to 2020 to treat acid reflux, from a CVS and Rite Aid in Pennsylvania. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac tablets, capsules, and syrup had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

202. Plaintiff Tammy DeWitt (for the purpose of this paragraph, "Plaintiff"), is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules, ranitidine tablets and capsules, from approximately 1990 to 2020 to treat acid reflux and irritable bowel syndrome (IBS), from a CVS and Walmart in Pennsylvania. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling,

storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

203. Plaintiff Gloria Colon (for the purpose of this paragraph, "Plaintiff"), is a citizen of Puerto Rico. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules, from approximately 1989 to 2019 to treat reflux, from a Walgreens and Farmacia Caridad in Puerto Rico. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

204. Plaintiff Annie Johnson (for the purpose of this paragraph, "Plaintiff"), is a citizen of South Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules from approximately 2013 to 2018 to treat acid reflux,

from a CVS in South Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

205. Plaintiff Jeffery Gunwall (for the purpose of this paragraph, "Plaintiff"), is a citizen of South Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 1990 to 2019 to treat acid reflux, from a Walgreens in South Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

206. Plaintiff Michael Futrell, both in his personal capacity and as guardian of his minor child, (for the purpose of this paragraph, "Plaintiff"), is a citizen of South Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules, ranitidine tablets and capsules, and Zantac syrup, from approximately 2015 to 2020 to treat indigestion, heartburn, acid reflux, and stomach upset, from a Costco pharmacy in Georgia, Walmart in South Carolina and Georgia, Walgreens in Florida, and OptumRx and Express Scripts mail-order pharmacies. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac tablets, capsules, and syrup had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

207. Plaintiff Sharon Mclellan (for the purpose of this paragraph, "Plaintiff"), is a citizen of South Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2005 to 2020 to treat heartburn, from a CVS pharmacy in South Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed

herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

208. Plaintiff William Hackler (for the purpose of this paragraph, "Plaintiff"), is a citizen of South Carolina. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules from approximately 1983 to 2016 to treat acid reflux, from small local pharmacies in Texas, and CVS, Walmart, and Walgreens in South Carolina. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

209. Plaintiff Areather Coleman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, approximately 2004 to 2020 to treat gastric reflux, heartburn, and gastroesophageal reflux disease (GERD), from

Kmart, Kroger, Phipps Pharmacy, Walmart, Dollar General, and Jackson Clinic pharmacy in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

210. Plaintiff Billie Walker (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2014 to 2019 to treat heartburn, from a Walgreens in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

211. Plaintiff Eva Broughton (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules, from approximately 2005 to 2020 to treat acid reflux and associated gastrointestinal problems, from Walmart in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

212. Plaintiff Dale Hunter (for the purpose of this paragraph, "Plaintiff") is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 1995 to 2019 to treat ulcers and other severe gastrointestinal medical issues, from a Kroger pharmacy, Family Dollar, Dollar General, and CVS in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed

herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

213. Plaintiff Jeffrey Garrett (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules from approximately 2015 to 2019 to treat indigestion, from a Walmart in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine tablets and capsules had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

214. Plaintiff Jennifer Fox (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2019 to 2020, to treat heartburn, from a Fry's Pharmacy in Arizona and SmartScripts mail-order pharmacy. As a direct and proximate result of

Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

215. Plaintiff Karen Hunter (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules, from approximately 1995 to 2019 to treat heartburn, from a Walmart in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine tablets and capsules had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

216. Plaintiff Kenneth Hix (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2000 to 2019 to treat heartburn, from CVS and Walgreens in Michigan. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac and ranitidine tablets and capsules had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

217. Plaintiff Keshia Paris-Bonner (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2013 to 2020 to treat acid reflux associated with asthma, from Walgreens and CVS in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Zantac and Ranitidine tablets and capsules had Defendants not breached their

express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

218. Plaintiff Lisa Lyle (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine syrup from approximately 2010 to 2020 to treat acid reflux, from Walgreens and CVS in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used ranitidine syrup had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

219. Plaintiff Pam Turner (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2017 to 2020 to treat stomach issues, from Food City in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff

purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine tablets and capsules had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

220. Plaintiff Rebecca Howard (for the purpose of this paragraph, "Plaintiff"), is a citizen of Tennessee. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2010 to 2019, to treat acid reflux, from Walmart in Tennessee. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

221. Plaintiff Agapito It Aleman (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2015 to 2017 to treat stomach issues and acid reflux, from Walmart in Texas. As a direct and proximate result of Defendants' breaches of

express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

222. Plaintiff Anselma Aldaco (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2014 to 2020 to treat a stomach ulcer, from Gaddis Pharmacy and Walmart in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

223. Plaintiff Christopher Johnson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2015 to 2020 to treat acid reflux, from a CVS pharmacy in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

224. Plaintiff Darlene Haley (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules and Zantac tablets and capsules, from approximately 2017 to 2020 to treat heartburn, from a Walmart in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted,

concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

225. Plaintiff Debra Washington (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2015 to 2019 to treat acid reflux, from a CVS pharmacy and Walgreens in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

226. Plaintiff Filiberto Garcia (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2010 to 2020 to treat heartburn, from a Walmart in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed

herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

227. Plaintiff Gina Martinez (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2012 to 2020 to treat heartburn and acid reflux, from Walgreens, Walmart, and H-E-B in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

228. Plaintiff Gregory Alan Wayland (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 1995 to 2019 to treat chronic pancreatitis, from Randalls grocery, CVS, Kroger, H-E-B, Costco, and Safeway in

Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

229. Plaintiff James Bell (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2000 to 2020 to treat heartburn and chronic rashes and hives, from a CVS pharmacy and Drug Shop Pharmacy in Texas and Humana mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

230. Plaintiff Jorge Pacheco (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 1977 to 2019 to treat ulcers, from a VA pharmacy and Walgreens in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

231. Plaintiff Liliana Del Valle (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2016 to 2019 to treat heartburn, from a CVS and Walgreens in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted,

concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

232. Plaintiff Maria Eames (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2012 to 2019 to protect stomach lining from anti-rejection medication after liver failure, from Walmart in Texas and Humana mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

233. Plaintiff Marianella Villanueva (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 1995 to 2020 to treat acid reflux, from an H-E-B, Walmart, CVS, and Family Dollar in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in

connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

234. Plaintiff Marilyn Abraham (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules, from approximately 2017 to 2019 to treat acid reflux from H-E-B and Walmart in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

235. Plaintiff Ronda Lockett (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and

OTC Zantac tablets and capsules, from approximately 1982 to 2020 to treat a bleeding ulcer and heartburn, from a CVS, Walgreens, and Walmart in Texas, as well as in Oklahoma. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

236. Plaintiff Sylvia Yoshida (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and prescription ranitidine tablets and capsules, from approximately 2006 to 2017 to treat heartburn, from a Walmart, Dollar General, and Family Dollar in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the

risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

237. Plaintiff Tina Howard (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2010 to 2015 to treat heartburn and gastric reflux, from a Walmart pharmacy in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

238. Plaintiff Tonya Overstreet (for the purpose of this paragraph, "Plaintiff"), is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2020 to treat heartburn, from a Save Mart in Texas. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing

Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

239. Plaintiff Scott Lillywhite (for the purpose of this paragraph, "Plaintiff"), is a citizen of Utah. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules, from approximately 2003 to 2019 to treat acid reflux, from Walgreens in California and Utah and Smith's and Exodus Healthcare in Utah. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

240. Plaintiff Teresa Waters (for the purpose of this paragraph, "Plaintiff"), is a citizen of Utah. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2017 to 2020 to treat acid reflux, from a Walmart and family grocery store in Utah. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent

misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

241. Plaintiff Eric Ragis (for the purpose of this paragraph, "Plaintiff"), is a citizen of Vermont. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules, from approximately 2010 to 2019 from CVS and Walgreens in Vermont. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

242. Plaintiff Lisa Ragis (for the purpose of this paragraph, "Plaintiff"), is a citizen of Vermont. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine

tablets and capsules, from approximately 2010 to 2019 from CVS and Walgreens in Vermont. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

243. Plaintiff Ronald Ragis (for the purpose of this paragraph, "Plaintiff"), is a citizen of Vermont. Plaintiff purchased and used Ranitidine-Containing Products, including OTC ranitidine tablets and capsules, from approximately 2010 to 2019 from CVS and Walgreens in Vermont. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-

Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

244. Plaintiff Cheryl Banks (for the purpose of this paragraph, "Plaintiff"), is a citizen of Virginia. Plaintiff purchased and used Ranitidine-Containing Products, including OTC and prescription Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2010 to 2019 to treat acid reflux from Walmart in Virginia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

245. Plaintiff Karen Foster (for the purpose of this paragraph, "Plaintiff"), is a citizen of Virginia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac and ranitidine tablets and capsules, from approximately 2016 to 2020 to treat a hernia, from CVS in Virginia and OptumRx mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing

Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

246. Plaintiff Lynn Costley (for the purpose of this paragraph, "Plaintiff"), is a citizen of Virginia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2013 to 2019 to treat acid reflux, from Express Scripts mail-order pharmacy. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

247. Plaintiff Dan Zhovtis (for the purpose of this paragraph, "Plaintiff"), is a citizen of Virginia. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac tablets and capsules and ranitidine tablets and capsules from approximately 2000 to 2019 to treat heartburn and acid reflux, from Rite Aid in New York, ShopRite in New Jersey, and Walmart in Virginia. As a direct and proximate result of Defendants' breaches of express and implied

warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

248. Plaintiff Renee Clark (for the purpose of this paragraph, "Plaintiff"), is a citizen of Vermont. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2011 to 2020 to treat acid reflux, from a Rite Aid and Walgreens in Vermont. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

249. Plaintiff Bridget Peck (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products, including prescription ranitidine tablets and capsules, from approximately 2012 to 2020 to treat gastroesophageal reflux disease (GERD), from a Rite Aid and Walgreens in Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

250. Plaintiff Darlene Mohn (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC ranitidine tablets and capsules, Zantac tablets and capsules, from approximately 1985 to 2020 to treat stomach issues, from a Safeway, Walgreens, Albertson's, and Fred Meyer in Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had

Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

251. Plaintiff Dave Garber (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 1990 to 2019 to treat acid reflux and heartburn, from a Chas Market Street Pharmacy and Safeway in Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

252. Plaintiff Jonathan Ferguson (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products, including OTC Zantac and ranitidine tablets and capsules, from approximately 1996 to 2017 to treat heartburn, from Walmart, Costco, Walgreens, Kmart, and Safeway in Oregon and Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties,

wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

253. Plaintiff Robert Dewitt (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products, including Zantac and ranitidine tablets and capsules, from approximately 1998 to 2020 to treat heartburn, from a Costco in Oregon and Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

254. Plaintiff Steve Fischer (for the purpose of this paragraph, "Plaintiff"), is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products, including both

prescription and OTC Zantac and ranitidine tablets and capsules, from approximately 2006 to 2019 to treat heartburn, from an Albertson's, Costco, Walmart, Rite Aid, and Bartel Drugs in Washington. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

255. Plaintiff Mynetta Hastings (for the purpose of this paragraph, "Plaintiff"), is a citizen of West Virginia. Plaintiff purchased and used Ranitidine-Containing Products, including both OTC and prescription ranitidine tablets and capsules, from approximately 2003 to 2019 to treat esophageal acid, from a CVS pharmacy in West Virginia and a Walmart in Ohio. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the

risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

256. Plaintiff Tina Andrade (for the purpose of this paragraph, "Plaintiff"), is a citizen of West Virginia. Plaintiff purchased and used Ranitidine-Containing Products, including prescription Zantac and ranitidine tablets and capsules, from approximately 2016 to 2020 to treat heartburn and acid reflux, from a CVS in West Virginia. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

257. Plaintiff Samantha Horton (for the purpose of this paragraph, "Plaintiff"), is a citizen of Wisconsin. Plaintiff purchased and used Ranitidine-Containing Products, including both prescription and OTC Zantac tablets and capsules and ranitidine tablets and capsules, from approximately 2007 to 2009 to treat acid reflux, from a Walgreens in Wisconsin. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-

Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

258. Plaintiff Wendy Quezaire (for the purpose of this paragraph, "Plaintiff"), is a citizen of Wisconsin. Plaintiff purchased and used Ranitidine-Containing Products, including prescription and OTC Zantac tablets and capsules, ranitidine tablets and capsules, from approximately 2005 to 2020 to treat acid reflux, from a Pick 'n Save pharmacy and CVS in Wisconsin. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiff purchased and ingested Ranitidine-Containing Products, which exposed Plaintiff to unsafe levels of NDMA. Plaintiff would not have purchased nor used Ranitidine-Containing Products had Defendants not breached their express and implied warranties, and misrepresented, omitted, concealed, and/or failed to timely disclose the risks associated with the use of Ranitidine-Containing Products. Thus, Plaintiff has suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

II. DEFENDANTS

259. Defendants are collectively composed of entities that invented, manufactured, distributed, labeled, marketed, advertised, distributed, stored, and sold ranitidine.

A. Brand-Name Manufacturer Defendants

1. Boehringer Ingelheim (BI)[5]

260. 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.

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

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

263. 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. Boehringer Ingelheim International GmbH is a citizen of Germany.

264. 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. Boehringer Ingelheim Promeco, S.A. de C.V. is a citizen of Mexico.

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[5] Defendant Boehringer Ingelheim also manufactured generic ranitidine under an Abbreviated New Drug Application ("ANDA"), 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.

265. Boehringer Ingelheim Pharmaceuticals, Inc. is a direct or indirect subsidiary of Boehringer Ingelheim Corporation and Boehringer Ingelheim USA Corporation, which are themselves wholly owned, directly or indirectly, by Boehringer Ingelheim International GmbH. Collectively, these entities shall be referred to as "Boehringer Ingelheim" or "BI."

2. GlaxoSmithKline (GSK)

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

267. 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.

268. 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. GlaxoSmithKline plc is a citizen of the United Kingdom.

269. GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are subsidiaries of GlaxoSmithKline plc. Collectively, these entities shall be referred to as "GSK."

3. Pfizer

270. 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. Pfizer Inc. is a citizen of Delaware and New York.

4. Sanofi

271. 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. Sanofi-Aventis U.S. LLC's sole member is Sanofi U.S. Services, Inc., a Delaware corporation with its principal place of business in New Jersey. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

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

273. Defendant Sanofi S.A. 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. Sanofi S.A. is a citizen of France.

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

275. Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are subsidiaries of Sanofi S.A.. Patheon Manufacturing Services LLC and Boehringer Ingelheim Promeco, S.A. de C.V. packaged and manufactured the finished Zantac product for Sanofi. Collectively, these entities shall be referred to as "Sanofi."

* * *

276. Defendants BI, GSK, Pfizer, and Sanofi, shall be referred to collectively as "Brand-Name Manufacturer Defendants." At all relevant times, Brand-Name Manufacturer Defendants have conducted business and derived substantial revenue from design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Ranitidine-Containing Products, including Zantac, within each of the States of the United States, the District of Columbia, and Puerto Rico.[6]

B. Generic Manufacturer Defendants

1. Ajanta

277. Defendant Ajanta Pharma USA Inc. is a New Jersey corporation with its principal place of business located at 440 U.S. Highway 22, Suite 150, Bridgewater, New Jersey 08807. Ajanta Pharma USA Inc. is a citizen of New Jersey.

278. Defendant Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at 9 Ajanta House Charkop, Kandivili (West), Mumbai, Maharashtra, India. Ajanta Pharma Ltd. is a citizen of India.

279. Ajanta Pharma USA Inc. is a subsidiary of Ajanta Pharma Ltd. Collectively, these entities shall be referred to as "Ajanta."

280. Defendant Ajanta purchased ranitidine and repackaged and/or relabeled it under Defendant's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Ajanta.

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

2. Amerisource

281. Defendant Amerisource Health Services, LLC d/b/a American Health Packaging, is a Delaware limited liability company with its principal place of business located at 2550 John Glenn Avenue, Suite A, Columbus, Ohio 43217. Amerisource Health Services, LLC's sole member is AmerisourceBergen Corporation, a Delaware corporation with its principal place of business in Pennsylvania. Amerisource Health Services, LLC is a citizen of Delaware and Pennsylvania.

282. Defendant AmerisourceBergen Corporation is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. AmerisourceBergen Corporation is a citizen of Delaware and Pennsylvania.[7]

283. Amerisource Health Services, LLC is a subsidiary of AmerisourceBergen Corporation. Collectively, these entities shall be referred to as "Amerisource."

3. Amneal

284. 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 Amneal Pharmaceuticals LLC is 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.

285. 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. The membership interest of Amneal Pharmaceuticals of New York, LLC is

[7] Defendant AmerisourceBergen Corporation is also a "Distributor Defendant" and is listed again under that heading below.

owned by Amneal Pharmaceuticals, Inc., through an intervening limited liability company. Amneal Pharmaceuticals of New York, LLC is a citizen of Delaware and New Jersey.

286. Defendant Amneal Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807. Defendant Amneal Pharmaceuticals, Inc. is a citizen of Delaware and New Jersey.

287. Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC are subsidiaries of Amneal Pharmaceuticals, Inc. Collectively, these entities shall be referred to as "Amneal."

288. Defendant Amneal purchased ranitidine and repackaged and/or relabeled it under Defendant Amneal's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Amneal.

4. Apotex

289. Defendant Apotex Corporation is a Delaware corporation with its principal place of business located at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex Corporation is a citizen of Delaware and Florida.

290. 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. Apotex Inc. is a citizen of Canada.

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

292. Defendant Apotex purchased ranitidine and repackaged and/or relabeled it under Defendant Apotex's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Apotex.

5. Aurobindo

293. Defendant Auro Health LLC is a New Jersey limited liability company with is principal place of business located at 2572 U.S. Highway 1, Lawrenceville, New Jersey 08648. The sole member of Auro Health LLC is Aurobindo Pharma USA, Inc., a Delaware corporation with its principal place of business located in New Jersey. Auro Health LLC is a citizen of Delaware and New Jersey.

294. Aurobindo Pharma USA, Inc. is a Delaware corporation with its principal place of business located at 279 Princeton Highstown Road, East Windsor, New Jersey 08520. Aurobindo Pharma USA, Inc. is a citizen of Delaware and New Jersey.

295. Defendant Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India. Aurobindo Pharma, Ltd. is a citizen of India.

296. Auro Health LLC and Aurobindo Pharma USA, Inc. are subsidiaries of Aurobindo Pharma, Ltd. Collectively, these entities shall be referred to as "Aurobindo."

297. Defendant Aurobindo purchased ranitidine and repackaged and/or relabeled it under Defendant Aurobindo's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Aurobindo.

6. Contract Pharmacal

298. Defendant Contract Pharmacal Corp. is a New York corporation with its principal place of business located at 135 Adams Avenue, Hauppauge, New York 11788. Contract Pharmacal Corp. is a citizen of New York.

7. Dr. Reddy's

299. 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. Dr. Reddy's Laboratories Inc. is a citizen of New Jersey.

300. Defendant Dr. Reddy's Laboratories, Ltd. 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. Dr. Reddy's Laboratories, Ltd. is a citizen of India.

301. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories, Ltd. are subsidiaries of Dr. Reddy's Laboratories SA., a non-party. Collectively, these entities shall be referred to as "Dr. Reddy's."

302. Defendant Dr. Reddy's purchased ranitidine and repackaged and/or relabeled it under Defendant Dr. Reddy's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Dr. Reddy's.

8. Geri-Care

303. Defendant Geri-Care Pharmaceuticals, Corp. ("Geri-Care") is a New York corporation with its principal place of business located at 1650 63rd Street, Brooklyn, New York 11204. Geri-Care is a citizen of New York.

304. Defendant Geri-Care purchased ranitidine and repackaged and/or relabeled it under Geri-Care's own brand. Therefore, all allegations referring to "Repackager Defendants" apply Geri-Care.

9. Glenmark

305. Defendant Glenmark Pharmaceuticals, Inc., USA is a Delaware corporation with its principal place of business located at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark Pharmaceuticals, Inc., USA is a citizen of Delaware and New Jersey

306. Glenmark Pharmaceuticals, Inc., USA is a subsidiary of Glenmark Pharmaceuticals Ltd., a non-party, and shall be referred to as "Glenmark."

307. Defendant Glenmark purchased ranitidine and repackaged and/or relabeled it under Defendant Glenmark's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Glenmark.

10. Heritage

308. Defendant Heritage Pharma Labs Inc. is a New Jersey corporation with its principal place of business located at 21 Cotters Lane, Suite B, East Brunswick, New Jersey, 08816-2050. Heritage Pharma Labs Inc. is a citizen of New Jersey.

309. Defendant Heritage Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 21 Cotters Lane, Suite B, East Brunswick, New Jersey 08816-2050. Heritage Pharmaceuticals, Inc. is a citizen of Delaware and New Jersey

310. Heritage Pharma Labs Inc. and Heritage Pharmaceuticals, Inc. are subsidiaries of Emcure Pharmaceuticals Ltd., a non-party. Collectively, these entities shall be referred to as "Heritage."

11. Hi-Tech

311. Defendant Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") is a Delaware corporation with its principal place of business located at 369 Bayview Avenue, Amityville, New York 11701. Hi-Tech is a citizen of Delaware and New York.

12. Lannett

312. Defendant Lannett Co., Inc. ("Lannett") is a Delaware corporation with its principal place of business located at 9000 State Road, Philadelphia, Pennsylvania 19136. Lannett is a citizen of Delaware and Pennsylvania.

313. Defendant Lannett purchased ranitidine and repackaged and/or relabeled it under Defendant Lannett's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Lannett.

13. Mylan

314. Defendant Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan Pharmaceuticals, Inc. is a citizen of West Virginia.

315. Defendant Mylan Institutional LLC is a Delaware limited liability company with its principal place of business located at 1718 Northrock Court, Rockford, Illinois 61103. The sole member of Mylan Institutional LLC is Mylan, Inc., a Pennsylvania corporation with is principal place of business in that state. Mylan Institutional LLC is a citizen of Pennsylvania.

316. Defendant Mylan, Inc. is a Pennsylvania corporation with its principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan, Inc. is a citizen of Pennsylvania.

317. Defendant Mylan Laboratories Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500 034, Hyderabad, India. Mylan Laboratories Ltd. is a citizen of India.

318. Mylan Pharmaceuticals, Inc., Mylan Institutional LLC, Mylan Laboratories Ltd., and Mylan, Inc. are subsidiaries of Mylan N.V., a non-party. Collectively, these entities shall be referred to as "Mylan."

319. Defendant Mylan purchased ranitidine and repackaged and/or relabeled it under Defendant Mylan's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Mylan.

14. Nostrum

320. Defendant Nostrum Laboratories Inc. ("Nostrum") is a New Jersey corporation with its principal place of business located at 1370 Hamilton Street, Summerset, New Jersey 08873. Nostrum Laboratories Inc. is a citizen of New Jersey.

321. Defendant Nostrum purchased ranitidine and repackaged and/or relabeled it under Defendant Nostrum's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Nostrum.

15. PAI

322. Defendant PAI Holdings, LLC f/k/a Pharmaceutical Associates, Inc., ("PAI") is a South Carolina limited liability company with its principal place of business located at 1700 Perimeter Road, Greenville, South Carolina 29605. Upon information and belief, the member(s) of PAI and the company itself are citizens of South Carolina.

16. Par Pharmaceutical

323. Defendant Par Pharmaceutical Inc. is a New York corporation with its principal place of business located at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical Inc. is a citizen of New York.

324. Par Pharmaceutical Inc. is a subsidiary of Endo International PLC, a non-party. Collectively, these entities are referred to as "Par Pharmaceutical."

17. Perrigo

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

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

327. L. Perrigo Co., and Perrigo Research & Development Company are subsidiaries of Perrigo Company, plc., a non-party. Collectively, these entities shall be referred to as "Perrigo."

328. Defendant Perrigo purchased ranitidine and repackaged and/or relabeled it under Defendant Perrigo's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Perrigo.

18. Sandoz

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

330. Sandoz Inc. is a subsidiary of Novartis AG., a non-party, and shall be referred to as "Sandoz."

19. Strides

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

332. Defendant Strides Pharma Global Pte. Ltd. is a corporation organized and existing under the laws of Singapore with its principal place of business located at 8 Eu Tong Sen Street, #15-93, The Central, Singapore 059818. Strides Pharma Global Pte. Ltd. is a citizen of Singapore.

333. Defendant Strides Pharma Science Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560 076, India. Strides Pharma Science Ltd. is a citizen of India.

334. Strides Pharma, Inc., Strides Pharma Global Pte. Ltd, and Strides Pharma Science Ltd. are subsidiaries of Strides Arcolab International Ltd., a non-party. Collectively, these entities shall be referred to as "Strides."

335. Defendant Strides purchased ranitidine and repackaged and/or relabeled it under Defendant Strides's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Strides.

20. Taro Pharmaceutical

336. Defendant Taro Pharmaceuticals U.S.A., Inc. is a New York corporation with its principal place of business located at Three Skyline Drive, Hawthorne, New York 10532. Taro Pharmaceuticals U.S.A., Inc. is a citizen of New York.

337. Defendant Ranbaxy Inc. is a Texas corporation with its principal place of business located at 2 Independence Way, Princeton, New Jersey 08540. Ranbaxy Inc. is a citizen of Texas and New Jersey.

338. Defendant Sun Pharmaceutical Industries, Inc., f/k/a Ranbaxy Pharmaceuticals Inc., is a Delaware corporation with is principal place of business located at 2 Independence Way, Princeton, New Jersey 08540. Sun Pharmaceutical Industries, Inc. is a citizen of Delaware and New Jersey.

339. Defendant Sun Pharmaceutical Industries Ltd. is corporation organized and existing under the laws of India with its principal place of business located at Western Express Highway Sun House, CTS No 201 B/1 Goregaon East, Mumbai, 400 063 India. Sun Pharmaceutical Industries Ltd. is a citizen of India.

340. Defendant Taro Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel with its principal place of business located at 14 Hakitor Street, Haifa Bay 2624761, Israel. Taro Pharmaceutical Industries Ltd. is a citizen of Israel.

341. Taro Pharmaceuticals U.S.A., Inc., Ranbaxy Inc., Sun Pharmaceutical Industries, Inc. (f/k/a Ranbaxy Pharmaceuticals Inc.), and Sun Pharmaceutical Industries Ltd. are subsidiaries of Taro Pharmaceutical Industries Ltd. Collectively, these entities shall be referred to as "Taro Pharmaceutical."

21. Teva

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

343. Defendant Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business located at 400 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals U.S.A., Inc. is a citizen of Delaware and Pennsylvania.

344. 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.

345. Defendant Teva Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel with its principal place of business located at 5 Basel Street, Petach Tikva, Israel, 4951033. Teva Pharmaceutical Industries Ltd. is a citizen of Israel.

346. Actavis Mid Atlantic LLC, Teva Pharmaceuticals U.S.A., Inc., and Watson Laboratories, Inc. are subsidiaries of Teva Pharmaceutical Industries Ltd. Collectively, these entities shall be referred to as "Teva."

22. Torrent

347. Defendant Torrent Pharma Inc. is a Delaware corporation with its principal place of business located at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920. Torrent Pharma Inc. is a citizen of Delaware and New Jersey.

23. Wockhardt

348. Defendant Wockhardt USA LLC is a Delaware limited liability company with its principal place of business located at 20 Waterview Boulevard, Parsippany, New Jersey 07054. Upon information and belief, the sole member of Wokhardt USA LLC is Wockhardt USA, Inc., a Delaware corporation with its principal place of business in New Jersey. Wockhardt USA LLC is a citizen of Delaware and New Jersey.

349. Wockhardt USA, Inc. is a Delaware corporation with its principal place of business located at 135 Route 202/206, Bedminster, New Jersey 07921. Wockhardt USA, Inc. is a citizen of Delaware and New Jersey.

350. Defendant Wockhardt, Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India. Wockhardt, Ltd. is a citizen of India.

351. Wockhardt USA LLC and Wockhardt USA, Inc. are subsidiaries of Wockhardt, Ltd. Collectively, these entities shall be referred to as "Wockhardt."

352. Defendant Wockhardt purchased ranitidine and repackaged and/or relabeled it under Defendant Wockhardt's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Wockhardt.

24. Zydus-Cadila

353. Defendant Zydus Pharmaceuticals (USA) Inc. is a New Jersey corporation with its principal place of business located at 73 Route 31 North, Pennington, New Jersey 08534. Zydus Pharmaceuticals (USA) Inc. is a citizen of New Jersey.

354. Cadila Healthcare Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Zydus Tower, Satellite Cross Roads, Sarkhej-Gandhinagar Highway, Amedabad 380 015, India. Cadila Healthcare Ltd. is a citizen of India.

355. Zydus Pharmaceuticals (USA) Inc. is a subsidiary of Cadila Healthcare Ltd. These entities operate under the trade name of, and shall be referred to as, "Zydus-Cadilla."

356. Defendant Zydus-Cadilla purchased ranitidine and repackaged and/or relabeled it under Defendant Zydus-Cadilla's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Zydus-Cadilla.

* * *

357. The Defendants identified in paragraphs 277 to 356 above shall be referred to collectively as "Generic Manufacturer Defendants." At all relevant times, Generic Manufacturer Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Ranitidine-Containing Products within each of the States.

C. Distributor Defendants

358. Distributors purchase bulk Ranitidine-Containing Products from Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants and then sell to Retailer Defendants. The distributor market is extremely concentrated, with three entities controlling approximately 92% of the volume: Defendants AmerisourceBergen Corporation; Cardinal Health, Inc.; and McKesson Corporation.

1. AmerisourceBergen

359. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. AmerisourceBergen is a citizen of Delaware and Pennsylvania.[8]

360. AmerisourceBergen purchased ranitidine and repackaged and/or relabeled it under AmerisourceBergen's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to AmerisourceBergen.

[8] Defendant AmerisourceBergen is also a "Generic Manufacturer Defendant" and is also listed under that heading above.

2. Cardinal Health

361. Defendant, Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its principal place of business located at 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal Health, Inc. is a citizen of Ohio.

362. Cardinal Health purchased ranitidine and repackaged and/or relabeled it under Cardinal Health's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Cardinal Health.

3. Chattem

363. Defendant Chattem, Inc. ("Chattem") is a Tennessee corporation with its principal place of business located at 1715 West 38th Street, Chattanooga, Tennessee 37409. Chattem is a citizen of Tennessee. Chattem is a wholly owned subsidiary of Sanofi S.A., a French corporation otherwise described above.

364. Chattem purchased ranitidine and repackaged and/or relabeled it under Chattem's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Chattem.

4. McKesson

365. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business located at 6535 North State Highway 161, Irving, Texas 75039. McKesson is a citizen of Delaware and Texas.

366. McKesson purchased ranitidine and repackaged and/or relabeled it under McKesson's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to McKesson.

* * *

367. Defendants, AmerisourceBergen, Cardinal Health, Chattem, and McKesson, shall be referred to collectively as "Distributor Defendants." At all relevant times, Distributor Defendants have conducted business and derived substantial revenue from their testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Ranitidine-Containing Products within each of the States.

D. Retailer Defendants

368. Retailers derived substantial revenue from marketing, handling, distributing, storing, and selling of Ranitidine-Containing Products within each of the States and territories of the United States. As described below, many retailers also used their own brand names on relabeled Ranitidine-Containing Products. They stand in direct contractual privity with consumers, insofar as retail pharmacies are the entities that dispensed or sold and received payment for the adulterated and/or misbranded Ranitidine-Containing Products for which Plaintiffs and Class members paid.

1. Albertson's

369. Defendant Albertson's Companies, Inc. is a Delaware corporation with a its principal place of business located at 132 East Lake Street, McCall, Idaho 83638. Albertson's Companies, Inc. is a citizen of Delaware and Idaho.

370. Defendant Safeway, Inc. is a Delaware corporation with its principal place of business located at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway, Inc. is a citizen of Delaware and California.

371. Defendant Safeway, Inc. purchased ranitidine and repackaged and/or relabeled it under Defendant Safeway's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Safeway, Inc.

372. Safeway, Inc. is a subsidiary of Albertson's Companies, Inc. Collectively, these entities shall be referred to as "Albertson's."

2. Amazon

373. Defendant Amazon.com, Inc. is Delaware corporation with its principal place of business located at 410 Terry Avenue North, Seattle, Washington 98109. Amazon.com, Inc. is a citizen of Delaware and Washington.

3. Costco

374. Defendant Costco Wholesale Corporation ("Costco") is a Washington corporation with its principal place of business located at 999 Lake Drive, Issaquah, Washington 98027. Costco is a citizen of Washington.

375. Defendant Costco purchased ranitidine and repackaged and/or relabeled it under Defendant Costco's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Costco.

4. CVS

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

377. Defendant CVS purchased ranitidine and repackaged and/or relabeled it under Defendant CVS's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant CVS.

378. CVS is the largest pharmacy healthcare provider in the United States. In 2015, CVS Health Corporation acquired Target Corporation's pharmacies and clinics. CVS defined herein includes any current or former Target Corporation pharmacy.

5. Dollar General

379. Defendant Dolgencorp, LLC ("Dollar General") is a Kentucky limited liability company with its principal place of business located at 100 Mission Ridge, Goodlettsville, Tennessee 37072. Dollar General Corporation is the sole member of Dolgencorp, LLC. Dollar General is a Tennessee corporation with its principal place of business in Tennessee. Dollar General is a citizen of Tennessee.

380. Defendant Dollar General purchased ranitidine and repackaged and/or relabeled it under Defendant Dollar General's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Dollar General.

6. Dollar Tree

381. Defendant Family Dollar, Inc. is a North Carolina corporation with its principal place of business located at 500 Volvo Parkway, Chesapeake, Virginia 23320. Family Dollar, Inc. is a citizen of North Carolina and Virginia.

382. Defendant Family Dollar, Inc. purchased ranitidine and repackaged and/or relabeled it under Defendant Family Dollar, Inc.'s own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Family Dollar, Inc.

383. Defendant Dollar Tree Stores, Inc. is a Virginia corporation with its principal place of business located at 500 Volvo Parkway, Chesapeake, Virginia 23320. Dollar Tree Stores, Inc. is a citizen of Virginia.

384. Family Dollar, Inc. is a subsidiary of Dollar Tree Stores, Inc., and shall collectively be referred to as "Dollar Tree."

7. Giant Eagle

385. Defendant Giant Eagle, Inc. ("Giant Eagle") is a Pennsylvania corporation with its principal place of business located at 101 Kappa Drive, Pittsburgh, Pennsylvania 15238. Defendant Giant Eagle, Inc. is a citizen of Pennsylvania.

8. HEB

386. Defendant H-E-B LP f/k/a HEB Grocery Company ("HEB") is a Texas limited partnership with its principal place of business located at 646 South Main Avenue, San Antonio, Texas 78204. Upon information and belief, the partners of H-E-B LP are citizens of Texas and, thus, H-E-B LP is a citizen of Texas.

387. Defendant HEB purchased ranitidine and repackaged and/or relabeled it under Defendant HEB's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant HEB.

9. Hy-Vee

388. Defendant Hy-Vee, Inc. is an Iowa corporation with its principal place of business located at 5820 Westown Parkway, West Des Moines, Iowa 50266. Hy-Vee, Inc. is a citizen of Iowa.

10. Kmart

389. Defendant Kmart Corporation is a Michigan corporation with its principal place of business located at 3333 Beverly Road, Hoffman Estates, IL 60179. Kmart Corporation is a citizen of Michigan and Illinois.

11. Kroger

390. Defendant The Kroger Co. is an Ohio corporation with its principal place of business located at 1014 Vine Street, Cincinnati, Ohio 45202. The Kroger Co. is a citizen of Ohio.

391. Defendant The Kroger Co. purchased ranitidine and repackaged and/or relabeled it under Defendant The Kroger Co.'s own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant The Kroger Co.

392. Defendant Smith's Food and Drug Centers, Inc. is an Ohio corporation with its principal place of business located at 1014 Vine Street, Cincinnati, Ohio 45202. Smith's Food and Drug Centers, Inc. is a citizen of Ohio.

393. Defendant Fred Meyer Stores, Inc. is an Ohio corporation with its principal place of business located at 3800 SE 22nd Avenue, Portland, Oregon 97202. Fred Meyer Stores, Inc. is a citizen of Ohio and Oregon.

394. Smith's Food and Drug Centers, Inc. and Fred Meyer Stores, Inc. are subsidiaries of the Kroger Co. Collectively, these entities shall be referred to as "Kroger."

12. Medicine Shoppe

395. The Medicine Shoppe International, Inc. is a Delaware corporation with its principal place of business located at 1100 North Lindbergh Boulevard, St. Louis, Missouri 63132. The Medicine Shoppe International, Inc. is a citizen of Delaware and Missouri.

396. The Medicine Shoppe International, Inc. is a subsidiary of Cardinal Health.[9] and shall be referred to as "Medicine Shoppe."

13. Price Chopper

397. Defendant Price Chopper Operating Co., Inc. is a New York corporation with its principal place of business located at 461 Nott Street, Schenectady, New York 12308. Price Chopper Operating Co., Inc. is a citizen of New York.

[9] Cardinal Health, Inc. is also a "Distributor Defendant" and is listed again under that heading above.

14. Publix

398. Defendant Publix Supermarkets, Inc. ("Publix") is a Florida corporation with its principal place of business located at 3300 Publix Corporate Parkway, Lakeland, Florida 33811. Publix is a citizen of Florida.

399. Defendant Publix purchased ranitidine and repackaged and/or relabeled it under Defendant Publix's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Publix.

15. Rite Aid

400. 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.

401. Defendant Rite Aid purchased ranitidine and repackaged and/or relabeled it under Defendant Rite Aid Corporation's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Rite Aid.

16. Shop-Rite

402. Defendant Shop-Rite Supermarkets, Inc. is a New Jersey corporation with its principal place of business located at 5000 Riverside Drive, Keasbey, New Jersey 08332. Defendant Shop-Rite Supermarkets, Inc. is citizen of New Jersey.

403. Shop-Rite Supermarkets, Inc. is a subsidiary of Wakefern Food Corporation, a non-party, and shall be referred to as "Shop-Rite."

17. Walgreens

404. 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.

405. 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.

406. 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.

407. Defendant Walgreens Boots Alliance, Inc. purchased ranitidine and repackaged and/or relabeled it under Defendant Walgreens Boots Alliance, Inc.'s own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Walgreens Boots Alliance, Inc.

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

18. Walmart

409. 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.

410. 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.

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

412. Defendant Walmart purchased ranitidine and repackaged and/or relabeled it under Defendant's own brand. Therefore, all allegations referring to "Repackager Defendants" apply to Defendant Walmart.

19. Winn Dixie

413. Defendant Winn Dixie Stores, Inc. is a Florida corporation with its principal place of business located 8928 Prominence Parkway, Building 200, Jacksonville, Florida 32256. Winn Dixie Stores, Inc. is a citizen of Florida.

414. Winn Dixie Stores, Inc. is a subsidiary of Southeastern Grocers, Inc., a non-party, and shall be referred to as "Winn Dixie."

* * *

415. Defendants identified in paragraphs 369 to 414 above shall be referred to collectively as "Retailer Defendants." At all relevant times, Retailer Defendants have conducted business and derived substantial revenue from marketing, handling, distributing, storing, and selling of Ranitidine-Containing Products within each of the States and territories of the United States.

E. Repackager Defendants

416. Repackagers take a finished or unfinished drug product and repackage that product into a different container without manipulating, changing, or affecting the composition or formulation of the drug. Relabelers change the content on an original manufacture's label to note the drug is distributed or sold under the relabeler's own name. Repackagers and relabelers, together, will be referred to as "Repackager Defendants," and will include Generic Manufacturer

Defendants, Distributor Defendants, and Retailer Defendants above who are also relabelers and/or repackagers.

1. Denton Pharma

417. Defendant Denton Pharma Inc. d/b/a Northwind Pharmaceuticals ("Denton Pharma") is a New York corporation with its principal place of business located at 119 Creamery Road, North Blenheim, New York 12131. Denton Pharma is a citizen of New York.

2. GSMS

418. Defendant Golden State Medical Supply, Inc. ("GSMS") is a California corporation with its principal place of business located at 5187 Camino Ruiz, Camarillo, California 93012. GSMS is a citizen of California.

3. Precision Dose

419. Defendant Precision Dose Inc. ("Precision Dose") is an Illinois corporation with its principal place of business located at 722 Progressive Lane South Beloit, Illinois 61080. Precision Dose is a citizen of Illinois.

* * *

420. The Defendants identified in paragraphs 417 to 419 above, combined with those Generic Manufacturer Defendants, Distributor Defendants, and Retailer Defendants above who are also relabelers and/or repackagers, shall be referred to collectively as "Repackager Defendants." At all relevant times, Repackager Defendants have conducted business and derived substantial revenue from the testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling of Ranitidine-Containing Products within each of the States and territories of the United States.

III. FACTUAL ALLEGATIONS[10]

A. The Creation of Ranitidine-Containing Products and Their Introduction to the Market

1. GSK Developed Zantac Through a Flurry of Aggressive Marketing Manuevers

421. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold prescription or OTC ranitidine under the brand name Zantac or a generic equivalent by either prescription or OTC. Defendants sold ranitidine in the following forms: injection, syrup, granules, tablets, and/or capsules.

422. Ranitidine belongs to a class of medications called histamine H_2-receptor antagonists ("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 (Tazac).

423. GSK[11]-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.

424. Zantac was developed specifically in response to the success of cimetidine.

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

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[10] Plaintiffs' reference to federal law herein is not an attempt to enforce it but to demonstrate that their claims do not impose obligations on Defendants beyond what is already required.

[11] GSK, as it's 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.

426. 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.

427. In 1983, the FDA granted approval to Glaxo to sell Zantac, pursuant to New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product – a "blockbuster." Indeed, ranitidine became the first prescription drug in history to reach $1 billion in sales. GSK manufactured its own prescription Zantac from 1983 until its withdrawal but ceased manufacturing its own API in 2014.[12]

428. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., increasing Zantac's U.S. sales force from 400 people to approximately 1,200. More salespersons drove more sales and blockbuster profits for GSK.

429. In 1993, GSK (through Glaxo Wellcome plc) entered into a joint venture with Pfizer-predecessor Warner-Lambert Co. to develop an OTC version of Zantac. In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC 75 mg effervescent tablets through NDA 20-745.

430. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their joint venture. 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 it was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK

[12] In 2014, GSK began using ranitidine API manufactured by Defendant Dr. Reddy's, Orchev Pharma PVT, and SMS Pharmaceuticals.

regained rights to sell OTC Zantac outside of the United States and Canada,[13] and it retained control over the Zantac trademark internationally.[14]

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

432. 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 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.

433. 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.

434. Throughout the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

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

436. 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

[13] GSK also still held the right to sell prescription Zantac in the United States.

[14] *See* Robert Langreth *Warner-Lambert and Glaxo End a Venture on Ulcer Drug Zantac*, WALL ST. J. (Aug. 4, 1998), https://www.wsj.com/articles/SB902188417685803000.

Zantac in the United States and Canada, as well as all intellectual property, research and development ("R&D"), and customer and supply contracts to Boehringer Ingelheim. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the Zantac OTC NDAs.

437. 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 and selling prescription Zantac tablets in 2017 . . . in the U.S."[15]

438. Boehringer Ingelheim Pharmaceuticals, Inc. owned and controlled the NDAs for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.[16]

439. In 2017, Boehringer Ingelheim sold the rights to OTC Zantac to Sanofi pursuant to a Sales Purchase Agreement ("SPA"). As part of this deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. However, Boehringer Ingelheim continued to manufacture all drugs subject to the SPA, including Zantac.

440. Sanofi has controlled the NDAs for OTC Zantac and marketed, distributed, and sold Zantac in the United States from January 2017, until it issued a recall in 2019.

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[15] GlaxoSmithKline, plc, *Annual Report 2019*, at 37, https://www.gsk.com/media/5894/annual-report.pdf.

[16] Boehringer Ingelheim also owned and controlled ANDA 074662.

441. 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.

442. Sanofi voluntarily recalled all brand-name OTC Zantac on October 18, 2019.

443. 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.

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

2. The Patents Expired, Allowing Generics to Enter the Market

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

446. When GSK and Pfizer's patent on the original OTC Zantac product expired, generic manufacturers were allowed to sell OTC ranitidine to consumers.

447. The FDA approved numerous generic manufacturers for the sale of prescription and OTC ranitidine through the ANDA process. Those generic manufacturers include:

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	OTC/RX
203694	Acic Pharmaceuticals Inc.	EQ 150 & 300 mg Base	Tablet; Oral	11/30/17	Rx
76124	Actavis Mid Atlantic, LLC	EQ 15 mg Base/ml	Syrup; Oral	2/21/07	Discontinued
209859	Ajanta Pharma Ltd.	EQ 150 & 300 mg Base	Capsule; Oral	9/27/18	Rx
77824	Amneal Pharmaceuticals of New York, LLC	EQ 150 & 300 mg Base	Tablet; Oral	10/13/06	Discontinued
78312	Amneal Pharmaceuticals	EQ 150 & 300 mg Base	Syrup; Oral	9/2/08	Rx
90054	ANDA Repository LLC	EQ 15 mg Base/ml	Syrup; Oral	11/15/10	Rx

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	OTC/RX
74488	Ani Pharmaceuticals Inc.	EQ 150 & 300 mg Base	Tablet; Oral	7/31/97	Discontinued
75212	Ani Pharmaceuticals Inc.	EQ 75 mg Base	Tablet; Oral	1/14/00	Discontinued
75296	Ani Pharmaceuticals Inc.	EQ 75 mg Base	Tablet; Oral	1/14/00	Discontinued
77426	Ani Pharmaceuticals Inc.	EQ 150 & 300 mg Base	Tablet; Oral	12/19/05	Discontinued
200172	Apotex Inc.	EQ 150 mg Base	Tablet; Oral	5/31/12	OTC
74680	Apotex Inc.	EQ 150 & 300 mg Base	Tablet; Oral	9/12/97	Rx
75167	Apotex Inc.	EQ 75 mg Base	Tablet; Oral	5/4/00	OTC
77602	Apotex Inc.	EQ 15 mg Base/ml	Syrup; Oral	9/17/07	Discontinued
207578	Aurobindo Pharma Ltd.	EQ 150 mg Base	Tablet; Oral	11/13/17	OTC
207579	Aurobindo Pharma Ltd.	EQ 150 mg Base	Tablet; Oral	11/13/17	OTC
211893	Appco Pharma LLC	EQ 150 & 300 mg Base	Capsule; Oral	4/5/19	Rx
90623	Aurobindo Pharma Ltd.	EQ 15 mg Base/ml	Syrup; Oral	7/28/10	Rx
211058	Aurobindo Pharma Ltd.	EQ 150 & 300 mg Base	Capsule; Oral	7/16/18	Rx
74764	Ben Venue Laboratories Inc. d/b/a Bedford Laboratories	EQ 25 mg Base/ ml	Injectable; Injection	11/19/04	Discontinued
74662	Boehringer Ingelheim	EQ 150 & 300 mg Base	Tablet; Oral	8/29/97	Discontinued
78684	Breckenridge Pharmaceutical Inc.	EQ 15 mg Base/ ml	Syrup; Oral	8/27/09	Rx
75094	Contract Pharmacal Corp.	EQ 75 mg Base	Tablet; Oral	6/21/99	Discontinued
75294	Dr Reddy's Laboratories, Ltd.	EQ 75 mg Base	Tablet; Oral	3/28/00	OTC
75742	Dr Reddy's Laboratories, Ltd.	EQ 150 & 300 mg Base	Capsule; Oral	11/29/00	Rx
76705	Dr Reddy's Laboratories, Inc.	EQ 150 & 300 mg Base	Tablet; Oral	7/27/05	Rx

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	OTC/RX
78192	Dr Reddy's Laboratories, Ltd.	EQ 150 mg Base	Tablet; Oral	8/31/07	OTC
78542	Glenmark Pharmaceuticals, Inc., USA	EQ 150 & 300 mg Base	Tablet; Oral	11/19/08	Rx
210243	Granules India, Ltd.	EQ 150 mg Base	Tablet; Oral	8/20/18	OTC
75165	Heritage Pharma Labs Inc.	EQ 150 & 300 mg Base	Tablet; Oral	9/30/98	Rx
91078	Hi Tech Pharmacal Co. Inc.	EQ 15 mg Base/ ml	Syrup; Oral	3/22/11	Rx
78890	Lannett Co., Inc.	EQ 15 mg Base/ ml	Syrup; Oral	7/1/10	Rx
91288	Lannett Co., Inc.	EQ 15 mg Base/ ml	Syrup; Oral	12/9/10	Rx
74023	Mylan Pharmaceuticals, Inc.	EQ 150 & 300 mg Base	Tablet; Oral	8/22/97	Discontinued
74552	Mylan Pharmaceuticals, Inc.	EQ 150 & 300 mg Base	Tablet; Oral	7/30/98	Discontinued
75497	Mylan Pharmaceuticals, Inc.	EQ 75 mg Base	Tablet; Oral	1/14/00	Discontinued
75564	Mylan Pharmaceuticals, Inc.	EQ 150 & 300 mg Base	Capsule; Oral	10/27/00	Discontinued
79076	Mylan Laboratories Ltd.	EQ 25 mg Base/ ml	Injectable; Injection	6/9/16	Rx
91091	Nostrum Laboratories Inc.	EQ 15 mg Base/ ml	Syrup; Oral	9/20/11	Rx
210681	Novitium Pharma LLC	EQ 150 & 300 mg Base	Capsule; Oral	11/23/18	Rx
75180	Par Pharmaceutical Inc.	EQ 300 mg Base	Tablet; Oral	1/28/99	Rx
76195	L. Perrigo Co.	EQ 75 mg Base	Tablet; Oral	8/30/02	OTC
91429	Perrigo Research & Development Company	EQ 150 mg Base	Tablet; Oral	5/11/11	OTC
77405	Pharmaceutical Associates Inc.	EQ 15 mg Base/ ml	Syrup; Oral	9/21/07	Rx
75000	Ranbaxy Pharmaceuticals Inc.	EQ 150 & 300 mg Base	Tablet; Oral	1/30/98	Discontinued
75254	Ranbaxy Pharmaceuticals Inc	EQ 75mg Base	Tablet; Oral	1/14/00	Discontinued

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	OTC/RX
78448	Ranbaxy Inc.	EQ 15 mg Base/ ml	Syrup; Oral	12/13/07	Discontinued
74467	Sandoz Inc.	EQ 150 & 300 mg Base	Tablet; Oral	8/29/97	Rx
74655	Sandoz Inc.	EQ 150 & 300 mg Base	Capsule; Oral	10/22/97	Rx
75519	Sandoz Inc.	EQ 75 mg Base	Tablet; Oral	9/26/02	Discontinued
200536	Strides Pharma Global Pte. Ltd.	EQ 150 mg Base	Tablet; Oral	6/28/11	OTC
201745	Strides Pharma Global Pte. Ltd.	EQ 75 mg Base	Tablet; Oral	2/29/12	OTC
205512	Strides Pharma Global Pte. Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	8/22/16	Rx
209160	Strides Pharma Global Pte. Ltd.	EQ 75 mg Base	Tablet; Oral	3/5/18	OTC
209161	Strides Pharma Global Pte. Ltd.	EQ 150 mg Base	Tablet; Oral	2/22/18	OTC
210010	Strides Pharma Global Pte. Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	8/1/18	Rx
75132	Sun Pharmaceutical Industries Ltd.	EQ 75 mg Base	Tablet; Oral	1/14/00	Discontinued
75439	Sun Pharmaceutical Industries Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	4/19/00	Discontinued
77476	Taro Pharmaceuticals USA, Inc.	EQ 15 mg Base/ ml	Syrup; Oral	6/13/11	Rx
75557	Teva Pharmaceuticals USA, Inc.	EQ 150 & 300 mg Base	Capsule; Oral	10/31/03	Discontinued
90102	Torrent Pharma, Inc.	EQ 15 mg Base/ ml	Syrup; Oral	5/26/09	Discontinued
210228	Unique Pharmaceutical Laboratories	EQ 150 mg Base	Tablet; Oral	8/30/19	OTC
210250	Unique Pharmaceutical Laboratories	EQ 75 mg Base	Tablet; Oral	8/30/19	OTC
211289	Vkt Pharma Private Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	1/31/19	Rx
74864	Watson Laboratories, Inc.	EQ 150 & 300 mg Base	Tablet; Oral	10/20/97	Discontinued
74777	West-Ward Pharmaceuticals International Ltd.	EQ 25 mg Base/ ml	Injectable; Injection	3/2/05	Rx

ANDA #	ANDA Holder	Strength	Dosage Form/ Route	Date Approved	OTC/RX
77458	West-Ward Pharmaceuticals International Ltd.	EQ 25 mg Base/ ml	Injectable; Injection	2/16/05	Rx
76760	Wockhardt, Ltd.	EQ 75 mg Base	Tablet; Oral	2/24/06	OTC
78653	Wockhardt, Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	11/26/07	Discontinued
78701	Wockhardt, Ltd.	EQ 150 mg Base	Tablet; Oral	11/12/09	Discontinued
78884	Wockhardt, Ltd.	EQ 75 mg Base	Tablet; Oral	7/31/08	Discontinued
79211	Wockhardt, Ltd.	EQ 15 mg Base/ ml	Syrup; Oral	5/26/09	Discontinued
79212	Wockhardt, Ltd.	EQ 15 mg Base/ ml	Syrup; Oral	2/23/09	Discontinued
75208	Wockhardt, Ltd.	EQ 150 & 300 mg Base	Tablet; Oral	12/17/98	Rx
91534	Zydus Pharmaceuticals (USA) Inc.	EQ 25 mg Base/ ml	Injectable; Injection	2/23/13	Rx

448. Despite generic entry, Brand-Name 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. Zantac was still ranked among the best-selling prescription drugs in the United States prior to its recall.[17] In 2016 alone, there were approximately 15,285,992 prescriptions written for Zantac.[18] And 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.

[17] ClinCalc.com, *The Top 200 of 2019*, https://clincalc.com/DrugStats/Top200Drugs.aspx. (last visited June 20, 2020).

[18] *Id.*

B. Defendants Knew and Had an Obligation to Further Investigate the Dangers of Their Ranitidine-Containing Products

1. Defendants Knew or Should Have Known of the NDMA Risk in Their Ranitidine-Containing Products

449. As early as 1981 – two years before Zantac entered the market – research showed elevated levels of NDMA, when properly tested.[19] This material fact was available in medical literature and would have been known by Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and any other manufacturer, distributor, or repackager of Ranitidine-Containing Products. This would not have been easily accessible to ordinary consumers, but it should have been accessed and reviewed by each company in the ranitidine supply chain.

450. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[20] Many metabolites were listed, though there is no indication that the study looked for NDMA. Defendants knew or should have known about this study.

451. Indeed, in that same year, Dr. Silvio de Flora published a note discussing the results of his experiments showing that ranitidine was converting 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, including foods that consumers were told they could consume shortly before or after ingesting ranitidine.[21] GSK was aware of this study and specifically responded to the note in an attempt to discredit it. Defendants knew or should have

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[19] *See supra*, ¶¶8, 496 & n.3 (discussing de Flora publication).

[20] P.F. 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. & APPLICATIONS 1, 161-68 (1981).

[21] *See infra* at ¶¶8, 496.

known about this scientific event as it was published in a popular scientific journal, and Defendants were obligated to investigate this issue properly through due diligence or otherwise.

452. 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.[22] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was rigged. 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 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 from its publication in 1987. Each Defendant 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.

453. As discussed in detail below, numerous studies that followed confirmed the risk of NDMA and its presence in Ranitidine-Containing Products.

454. Upon information and belief, no Defendant ever used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with

[22] J. Meyrick Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 28-6 GUT 726, 726-38 (1987), https://gut.bmj.com/content/gutjnl/28/6/726.full.pdf.

their ranitidine NDA. That is because mass spectrometry requires heating of up to 130 degrees Celsius, which can result in the formation of excessive amounts of nitrosamines. Had Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants used a mass spectrometry assay, it would have revealed large amounts of NDMA in ranitidine. They chose not to do so.

455. In 2019, Valisure ran tests on Zantac and discovered the link between Zantac and its generics and the carcinogen NDMA. Valisure first notified the FDA of its initial findings in June of 2019.

456. On September 13, 2019, Valisure filed a citizen petition with the FDA asking the agency to recall all products that contain ranitidine[14] and provided the WHO and IARC with copies of the petition.

457. Valisure conducted follow-up testing and determined that the Zantac batch tested was not contaminated, but rather, the molecule within the drug itself is unstable and can form NDMA, particularly in the conditions found in the stomach.[15]

458. From that point forward, Defendants could no longer ignore and/or conceal the truth that their Ranitidine-Containing Products are unsafe and unfit for human use.

2. NDMA Has Long Been Deemed a Probable Carcinogen, with Well-Established Dangerous Properties

459. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes[.]"[23] 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

[23] EPA, *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.

"NDMA has caused cancer in nearly every laboratory animal tested so far."[24] NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

460. Both the EPA and the IARC classify NDMA as a probable human carcinogen.[25]

461. 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 frog. 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."[26]

462. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[27]

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[24] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, GLOBE & MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, 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"); S.A. Kyrtopoulos, *DNA Adducts in Humans after Exposure to Methylating Agents*, 405 MUTATION RES. 2, 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").

[25] *See* EPA *Technical Fact Sheet*, *supra* n.23; International Agency for Research on Cancer (IARC) - Summaries & Evaluations, *N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

[26] IARC, *Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds*, Vol. 17, 151-152 (May 1978).

[27] *See* EPA *Technical Fact Sheet*, *supra* n.23.

463. The U.S. Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[28] This classification is based upon the 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.[29]

464. The FDA considers NDMA a chemical that "could cause cancer" in humans.[30]

465. The WHO states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[31]

466. 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.

467. 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.

468. The no-observed-adverse-effect level ("NOAEL") is the level of exposure at which there is no biologically significant increase in the frequency or severity of any adverse effects of a chemical. Due to NDMA's ability to affect deoxyribonucleic acid ("DNA") at a microscopic level,

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[28] *Id.* at 3.

[29] *Id.*

[30] FDA, *Statement Alerting Patients and Healthcare 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.

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

there is no NOAEL for NDMA. This means any amount of NDMA exposure increases the risk of cancer.

469. The FDA has set an acceptable daily intake level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA per day will increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.[32] For reference, one filtered cigarette contains between 5 to 43 ng of NDMA.

470. 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.

471. 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.

472. Further, animals exposed to NDMA during pregnancy birthed offspring with elevated rates of cancer in the liver and kidneys.

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[32] FDA, *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartin, Losartin, and Irbesartan), FDA updates table of interim limits for nitrosamine inpurities in ARBs* (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.

473. NDMA is a very small molecule, which allows it to freely pass through all areas of the body, including the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for use by pregnant women and young children for years.

474. In addition to the carcinogenic nature of NDMA itself, NDMA breaks down into various derivative molecules that, themselves, are also associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestines (including colon).

475. Research shows that lower levels of NDMA, *e.g.*, 40 ng, are fully metabolized in the liver, but high doses enter the body's general circulation.

476. Exposure to high levels of NDMA has been linked to liver damage in humans.[33]

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

478. 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.

479. 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[.]"[34]

480. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[35]

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[33] *See* EPA *Technical Fact Sheet*, *supra* n.23.

[34] *Id.*

[35] *See* EPA, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

481. In addition to the overwhelming animal data linking NDMA to cancer, numerous human epidemiological studies exploring the effects of dietary exposure to various cancers consistently show increased risks of various cancers. Notably, however, the exposure levels considered in these studies are a very small fraction of the exposures from a single ranitidine capsule.

482. 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 ng/day.[36]

483. 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 ng/day.[37]

484. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 ng/day.[38]

485. 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

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[36] D. Pobel et al., *Nitrosamine, Nitrate and Nitrite in Relation to Gastric Cancer: a Case-Control Ctudy in Marseille, France*, 11 EUR. J. EPIDEMIOLOGY 1, 67-73 (Feb. 1995).

[37] C. La Vecchia et al., *Nitrosamine Intake and Gastric Cancer Risk*, 4 EUR. J. CANCER. PREVENTION 6, 469-74 (Dec. 1995).

[38] M. A. Rogers et al., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cancer*, 5 CANCER EPIDEMIOLOGY BIOMARKERS PREVENTION 1, 29-36 (Jan./Feb. 1995).

carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[39]

486. 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, pharynx, prostate, and brain cancer.[40]

487. 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.[41]

488. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.[42]

489. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA can: (a) exacerbate existing but dormant (*i.e.*, not malignant) cancers; (b) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (c) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause

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[39] P. 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'L. J. CANCER 6, 852-56 (Mar. 15, 1999).

[40] K. Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Zmong a Cohort of Rubber Workers*, 57 OCCUPATIONAL & ENVTL. MED. 180-87 (Mar. 2000).

[41] Yet Hua 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 5, 1053-61 (May 2011).

[42] Yun 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 (Mar. 28, 2014).

of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

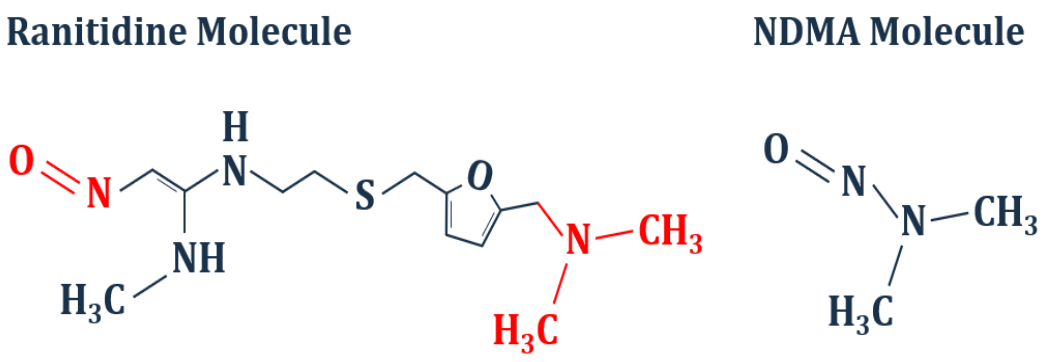
490. NDMA is also known to be genotoxic – meaning it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[43]

3. Ranitidine Transforms into NDMA Within the Body

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

492. Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H_3C-N-CH_3 (DMA) on the other side to form NDMA.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



493. 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

[43] WHO, *Guidelines for Drinking-Water Quality, supra* n.31.

contamination of the U.S. water supply.[44] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[45]

494. Ranitidine leads to NDMA exposure in four ways: (a) formation of NDMA in the human digestive system; (b) formation of NDMA due to an enzymatic reaction throughout the human body; (c) formation of NDMA over time under normal storage conditions and which increases significantly when exposed to heat; and (d) formation of NDMA during the manufacturing process.

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

495. 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 (O=N) and the DMA molecule (H_3C-N-CH_3) break off and reform as NDMA.

496. In 1981, Dr. 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."[46] 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

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[44] T. Ogawa et al., *Purification and Properties of a New Enzyme, NG,NG-Dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. BIO. CHEM. 17, 10205-209 (June 15, 1989).

[45] William A. Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENVTL. ENGINEERING SCI. 5, 389-404 (Sept. 2003).

[46] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, *supra* n.3.

our experimental conditions."[47] 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[.]***"[48] Shockingly, 17 years after Dr. de Flora's warning, GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced [*i.e.*, high-nitrite foods] heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal."[49]

497. 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.[50]

498. This response reflects GSK's reputation for "adopting the most combative, scorched-earth positions in defense of its brands."[51] 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.

499. 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

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47 *Id.*

48 *Id.*

49 *See* U.S. Dept. of Health & Human Services, Center for Drug Evaluation and Research, Approval Letter (Jun. 8, 1998), https://www.accessdata.fda.gov/drugsatfdadocs/nda/98/20520s1_Zantac.pdf. So, GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

50 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.

51 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/.

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,[52] 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.[53]

500. In its submission to the FDA, GSK explained that the level of nitrite present would be unrealistic and, thus, these results had no "practical clinical significance."[54]

> 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.

501. Around this same time – 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.[55] Remarkably, in the study that was presented to the FDA, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that

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

[53] 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.

[54] 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.

[55] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

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 developing NDMA and, in turn, cancer, but then dismissed this risk because people were 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.

502. GSK knew – and indeed specifically admitted – that ranitidine could react with nitrite in the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach.

503. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[56] 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 rigged. 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 out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being***

[56] Thomas et al., *supra* n.22.

recorded."[57] In other words, GSK intentionally rigged the study to exclude the very samples most likely to contain a dangerous carcinogen.

504. In 1983, the same year Zantac obtained approval from the FDA, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[58] 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."[59]

505. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[60] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine."[61] 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 meal[s]."[62] 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.

506. The high instability of the ranitidine molecule was further elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms

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57 *Id.*

58 Annalisa Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOXICOLOGY LETTERS 1-2, 97-102 (Aug. 1983).

59 *Id.*

60 Silvio de Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 CARCINOGENESIS 3, 255-60 (1983).

61 *Id.*

62 *Id.*

for the breakdown of ranitidine were proposed.[63] 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.

507. In 2016, researchers at Stanford University conducted an experiment on healthy volunteers.[64] 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. 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. This study directly demonstrates that unsafe levels of NDMA are formed in the human body as a result of ranitidine ingestion. 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. As such, the observed 47,000 ng likely only captured 1/100 of the actual NDMA levels in the human body.

508. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile nitrite and dimethylamine ("DMA") group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing of ranitidine batches shows NDMA levels so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

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[63] Julien Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 ENVTL. SCI. TECH. 20, 11095-103 (2012).

[64] Teng Zeng & William A. Mitch, *Oral Intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 CARCINOGENESIS 6, 625-34 (June 2016).

509. Valisure is an online pharmacy that also runs an analytical laboratory that is International Organization for Standardization ("ISO") 17025 accredited – 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. 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.

510. In its September 9, 2019 Citizen's Petition to the FDA, [65] Valisure disclosed as part of its testing of Ranitidine-Containing Products that every lot tested showed exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended gas chromatography-mass spectrometry ("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.[66]

511. Valisure's September 2019 testing showed, on average, 2,692,291 ng of NDMA in a 150 mg ranitidine tablet. This testing demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures and in a high nitrite environment, such as in the human stomach. 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.

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

[66] FDA, *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, by GC/MS-Headspace* (Jan. 28, 2019), https://www.fda.gov/media/117843/.

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

512. Following its September 2019 testing, Valisure developed a low temperature GC/MS method that could 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.

513. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF") (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") (SIF 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 through 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 real environment of a human stomach.

514. Indeed, Ranitidine-Containing Products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[67]

515. 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).

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
SGF	Not Detected	Not Detected
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

516. 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 consume 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).

517. Following the release of Valisure's 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 SGFSIF models

[67] *See, e.g.*, iSpot.tv, *Zantac TV Commercial, "Family Taco Night*," https://www.ispot.tv/ad/dY7n/zantac-family-taco-night (last visited June 20, 2020); YouTube, *Zantac:Spicy* (Apr. 15, 2009), https://youtu.be/jzS2kuB5_wg; YouTube, *Zantac® Heartburn Challenge* (Oct, 8, 2015), https://youtu.be/qvh9gyWqQns; YouTube, *Zantac Heartburn Funny TV Commercial* (Feb. 26, 2005), https://youtu.be/Z3QMwkSUlEg.

to use with the liquid chromatography-high resolution mass spectrometry ("LC-HRMS") 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. The testing showed unacceptable levels of NDMA.

518. The scientific data and literature demonstrates that in 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 breaks down into levels of NDMA that would dramatically increase a person's risk of developing cancer.

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

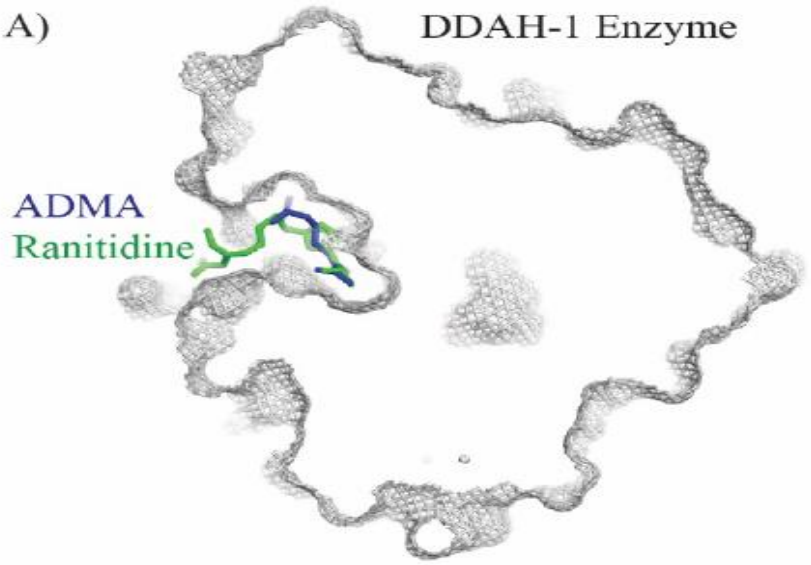
519. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs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

520. 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]."[68]

[68] Ogawa et al., *supra* n.44.

521. 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

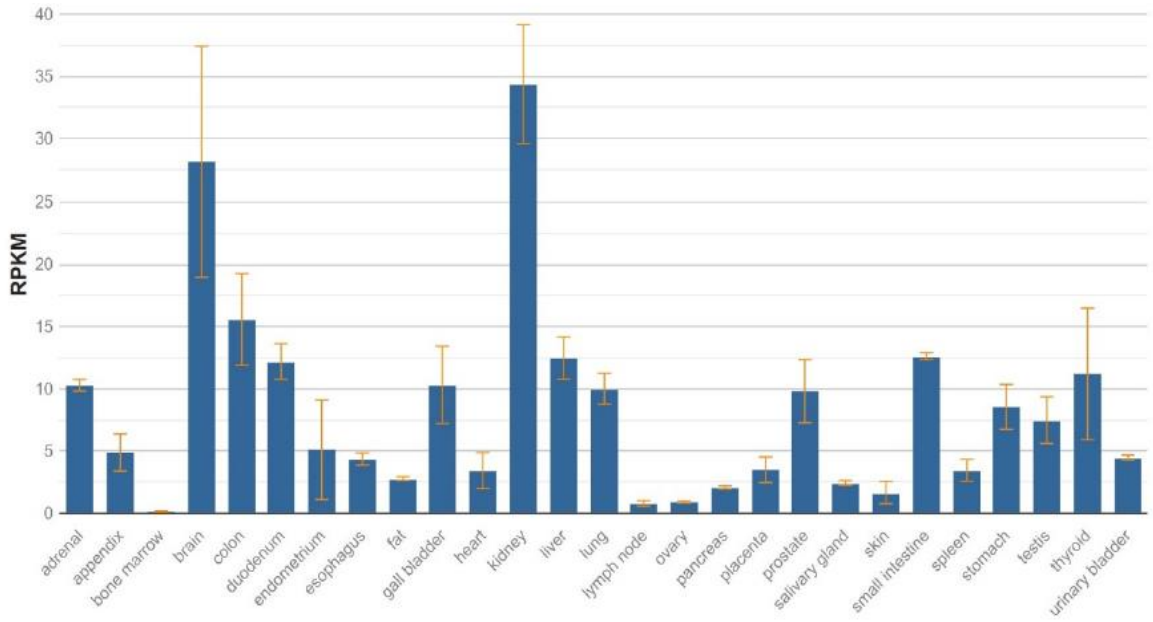


	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

522. These results indicate 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.

523. 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



524. 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. 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.

525. 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.

c. Formation of NDMA from Exposure to Heat and/or Over Time

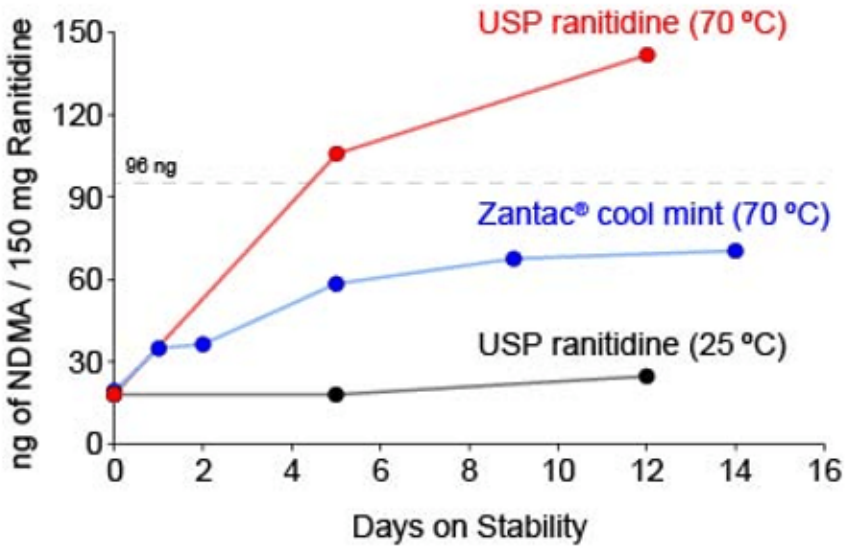
526. The conversion of ranitidine into NDMA through exposure to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that NDMA formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method (but also specifically developed a detection protocol that did not use heat).

527. 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.[69]

528. On January 2, 2020, Emery Pharma ("Emery"), 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. The following diagram reveals how NDMA accumulates over time when exposed to 70 ˚C:

[69] FDA, *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine), FDA Provides Update on Testing of Ranitidine for NDMA Impurities* (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

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



529. The researchers cautioned that: NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, ***which would be routinely reached during shipment and during storage***.[70]

530. The results of this data demonstrate that when exposed to heat, even through normal transport and storage, the breakdown of the ranitidine molecule into NDMA is exacerbated and/or accelerated – a point underscored by the FDA's swift removal of the product from the market.

d. Formation of NDMA in the Manufacturing Process

531. Recent testing conducted under the auspices of the FDA involving a number of drugs within the last two years also demonstrates that NDMA can form during the manufacturing process.

[70] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 7, 2020), https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/ (last visited June 20, 2020).

532. On July 13, 2018, the FDA announced the first of what would be many recalls of Valsartan and other angiotensin receptor blocker ("ARB") drugs used to treat high blood pressure, such as losartan and irbesartan.[71]

533. Specifically, the recalls were due to NDMA and other nitrosamines being present in the APIs manufactured by four API manufacturers located in China and India.

534. According to the Council on Foreign Relations, "about 80 percent of the active pharmaceutical ingredients (APIs) used to make drugs in the United States are said to come from China and other countries like India."[72]

535. As the FDA's investigation into the ARB contamination continued, it became clear that NDMA had made its way into the API through the use of recovered solvents or as a result of using less expensive solvents during the manufacturing process.[73]

536. Similarly, API was noted as a possible source of NDMA in Ranitidine-Containing Products: "Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA."[74]

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[71] FDA, *FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity* (July 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

[72] Yanzhong Huang, *U.S. Dependence on Pharmaceutical Products from China* (Aug. 14, 2019), https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

[73] FDA, *FDA announces voluntary recall*, *supra* n.71.

[74] FDA, *Lannett Issues Voluntary Nationwide Recall of Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/ml due to an Elevated Level of the Unexpected Impurity, N-Nitrosodimethylamine* (Oct. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lannett-issues-voluntary-nationwide-recall-ranitidine-syrup-ranitidine-oral-solution-usp-15mgml-due.

537. The FDA's early testing of ranitidine was conducted without utilizing heat and without subjecting the pills to gastric conditions. This testing nonetheless revealed unacceptable levels of NDMA.[75]

4. Evidence Directly Links Ranitidine Exposure to Cancer

538. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with cancer.

539. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[76]

540. 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.[77]

541. In another comprehensive epidemiological study looking at various cancer risks and histamine H_2 blockers, including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[78] Of particular

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[75] FDA, *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine), FDA Alerts Patients and Health Care Professionals to Amneal's Volutary Recall of Nizatidine* (Apr. 16, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[76] D. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2, 250-54 (Feb. 2004).

[77] Robert W. Mathes et al., *Relationship Between Histamine2-Receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1, 67-72 (2008).

[78] Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149-55 (2000).

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 the risk of pancreatic cancer with ranitidine use.

542. 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 finding is particularly notable as the authors adjusted for variables.[79]

543. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H_2 blockers.[80] 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 blockerss and hepatocellular carcinoma, a type of liver cancer.

544. 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.[81] These cancers

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[79] 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 (July 2018).

[80] Y.H.J. Shao et al., *Association Between Proton Pump Inhibitors and the Risk of Hepatocellular Carcinoma*, 48 ALIMENTARY PHARMACOLOGY & THERAPEUTICS 4, 460-68 (Aug. 2018).

[81] Mathes et al., *supra* n.77; *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 (Apr. 28, 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 (Mar. 2014); A.H. 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 et al., *Acid-Suppressing Therapies and Subsite-Specific Risk of Stomach Cancer*, 116 BRIT. J. CANCER, 1234-38 (2017).

include the following: breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of breast, testicular, thyroid, and kidney cancer.[82]

C. Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants Made Misrepresentations and Omissions in the Advertising of Ranitidine-Containing Products

1. Brand-Name Manufacturer Defendants' and Generic Manufacturer Defendants' Labels Were Misleading and Omitted Material Information and Warnings that Should Have Been Apparent to Them through Stability Testing

545. 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[,]"[83] and to conform to requirements governing the appearance of the label.[84]

546. "Labeling" encompasses all written, printed, or graphic material accompanying the drug or device,[85] and therefore broadly encompasses nearly every form of promotional activity, including not only package inserts but also advertising.

547. "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." (Footnote omitted.)[86]

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

[83] 21 C.F.R. §201.5.

[84] 21 C.F.R. §201.15.

[85] *Id.*; Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. 14,286 (Mar. 16, 2000).

[86] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

548. 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."[87] 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."[88]

549. The purpose of stability testing is, in part, to determine "appropriate storage conditions and expiration dates."[89] 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."[90] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies described in §211.166."[91]

550. 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."[92] Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and

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87 22 C.F.R. §211.166(a).

88 *Id.*

89 *Id.*

90 21 C.F.R. §211.137(a).

91 21 C.F.R. §211.137(b).

92 Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding,43 Fed. Reg. 45,014, 45,059 (Sept. 29, 1978).

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."[93]

551. 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."[94]

552. 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.[95]

553. Some of the requirements in those regulations require a brand or generic manufacturer of an approved drug to obtain FDA approval before implementing a label change.[96]

554. 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.[97]

555. 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,

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93 *Id.*

94 21 C.F.R. §211.166(b).

95 *See* 21 C.F.R. §§314.70, 314.97(a) (requiring generics to comply).

96 21 C.F.R. §314.70(b).

97 21 C.F.R. §314.70(c)(3), (c)(6).

quality, purity, or potency that it purports or is represented to possess."[98] "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."[99]

556. 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"[100] – or to ensure that the drug is shipped and stored under appropriate conditions.

557. 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[.]"[101]

558. 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

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98 21 C.F.R. §314.70(c)(6)(i).

99 International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances, 65 Fed. Reg. 83,041, 83,042 (Dec. 29, 2000).

100 21 C.F.R. §211.137(a).

101 21 C.F.R. §§314.70(c)(6)(iii)(A), (C), (D).

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[.]"[102]

559. 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."[103]

560. At no time did any Brand-Name Manufacturer Defendants or Generic Manufacturer Defendants attempt to include a warning about NDMA levels in ranitidine and its association with cancer, and the FDA never rejected such a warning. Manufacturer Defendants holding the NDAs had the ability to unilaterally add an NDMA and/or cancer warning to the labels of Ranitidine-Containing Products (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any such Manufacturer Defendant attempted to add an NDMA warning to the label of its Ranitidine-Containing Products (either for prescription or OTC), the FDA would not have rejected it and/or would have ordered the Ranitidine-Containing Products recalled from the market.

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

562. Based on the public scientific information available starting in 1983 (or earlier), Brand-Name Manufacturer and Generic Manufacturer Defendants knew or should have known

[102] 21 C.F.R. §314.70(d)(2)(ix).

[103] 21 C.F.R. §314.70(d)(2)(vi).

that the breakdown of ranitidine into NDMA is exacerbated and/or accelerated through exposure to heat and/or over time in storage, and that this increased the risk of cancer.

563. At no time did any Brand-Name Manufacturer or Generic Manufacturer Defendant change its label to shorten the expiration date or alter the safe shipping and storage conditions of its Ranitidine-Containing Product, and the FDA never rejected such changes. Both Brand-Name Manufacturer Defendants and 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 Brand-Name Manufacturer or Generic Manufacturer Defendant attempted such label changes, the FDA would not have rejected them.

564. Because they failed to warn that Ranitidine-Containing Products contained or broke down into NDMA, Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants made false statements in the labeling of their products and omitted material information regarding the drug's safety.

565. Because they failed to include appropriate expiration dates on their products, Brand-Name Manufacturer and Generic Manufacturer Defendants made false statements in the labeling of their products and omitted material information regarding the drug's safety.

566. Because they failed to include proper storage instructions on their products, Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants made false statements in the labeling of their products and omitted material information regarding the drug's safety.

2. Brand-Name Manufacturer Defendants Developed and Implemented a Pervasive Marketing Scheme to Mislead the Consuming Public and Others

567. Having created an inherently unstable and unsafe product, Brand-Name Manufacturer Defendants had to mislead consumers and health professionals into believing Zantac

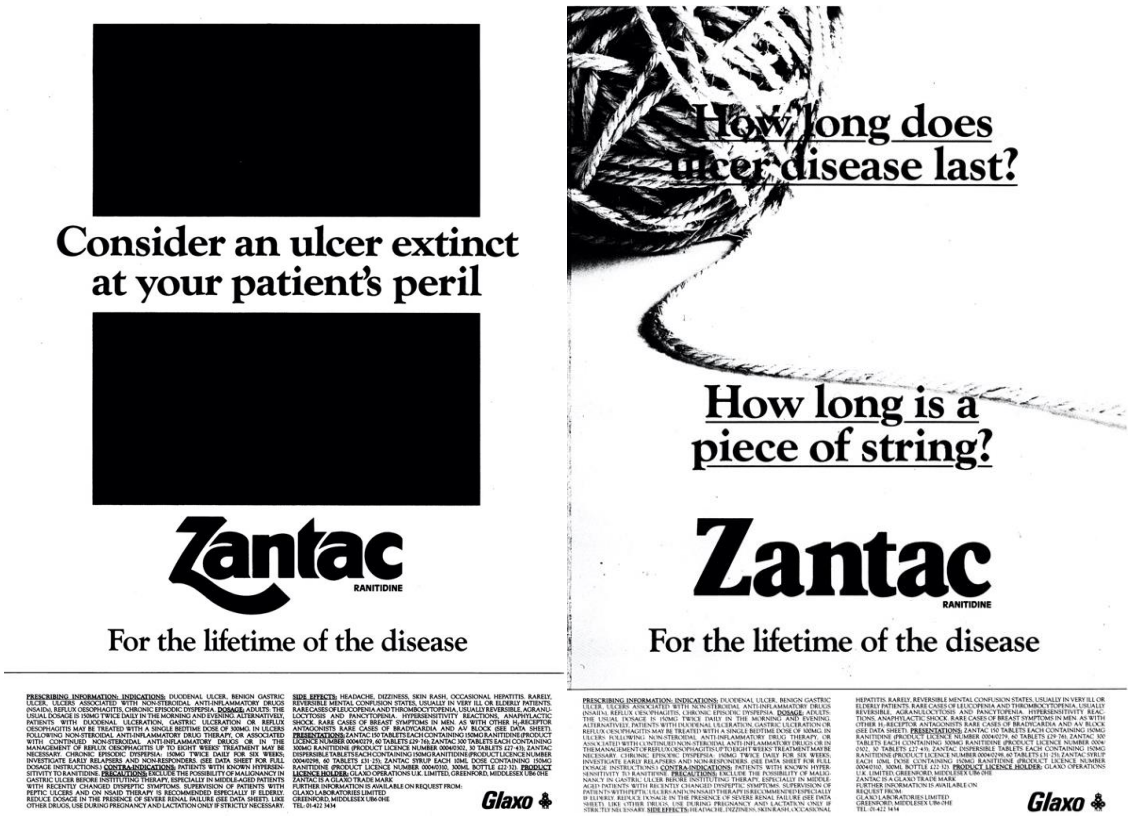
was safe, including safe for use with chronic conditions and for fast, immediate relief with nitrite- and nitrate-rich foods. Brand-Name Manufacturer Defendants thus engaged in a pervasive and decades-long campaign of misrepresentations and omissions to convince consumers that Zantac was safe and to conceal the existence of, and risks posed by, NDMA.

568. Brand-Name Manufacturer Defendants devised and knowingly carried out a material scheme to defraud consumers by misrepresenting the safety, and concealing the true health risks, of Zantac. The marketing campaign was national in scope and spanned decades, and although it came via separate missives, the fundamental message was uniform: Zantac is safe, can be used frequently and with high-nitrate and -nitrite foods, and poses no serious health risks, such as those associated with consumption of NDMA – a known human carcinogen.

a. Brand-Name Manufacturer Defendants Marketed Zantac as a Safe Treatment Method for Chronic Conditions to Health Professionals and as a Medication Trusted and Recommended by Doctors to Consumers

569. Brand-Name Manufacturer Defendants presented Zantac as being a safe and effective treatment for chronic conditions, and touted Zantac as being the treatment method trusted and recommended by doctors. However, despite knowing that Ranitidine-Containing Products presented a dangerous and unreasonable risk of injury to its end-users through elevated levels of NDMA, Brand-Name Manufacturer Defendants wholly omitted any information from their advertisements that disclosed the serious health risks posed by use or ingestion of Ranitidine-Containing Products.

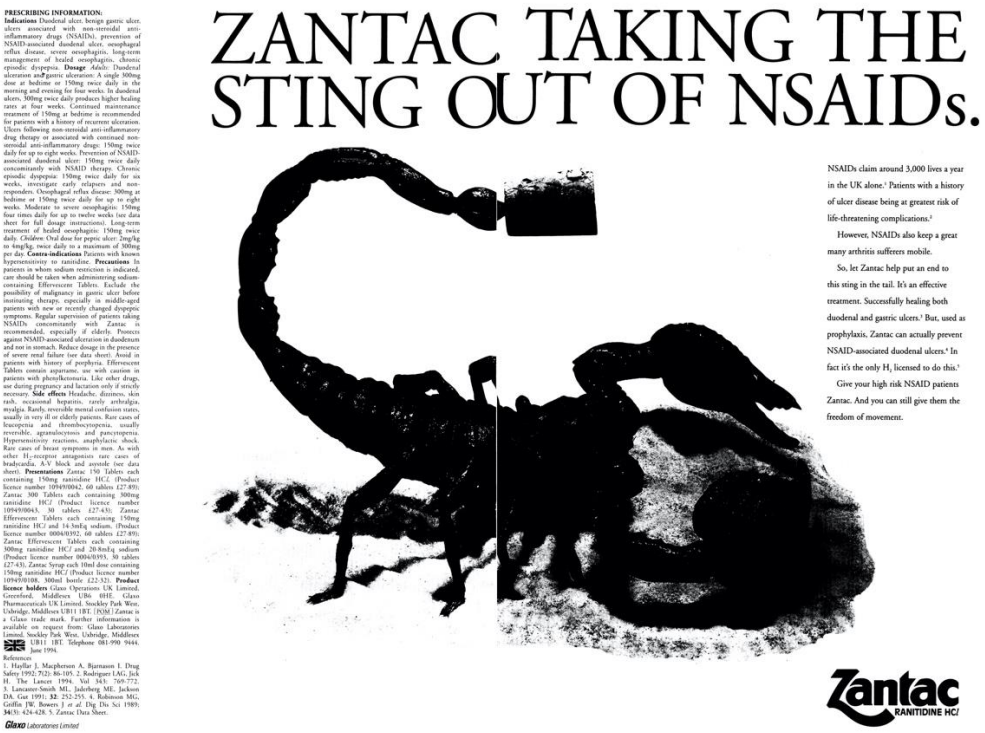
570. For example, in 1990, GSK ran ads in *Gut*, an international medical journal published by the British Society of Gastroenterology, representing that Zantac was a medication that could be taken "[f]or the lifetime of the disease":[104]



571. From at least 1994-1995, GSK also placed ads in *Gut*, touting Zantac as an effective prophylaxis to be used in conjunction with NSAIDs to prevent NSAID-associated duodenal ulcers:[105]

[104] *Advertising*, 31-5 GUT 489 (May 1, 1990), https://gut.bmj.com/content/gutjnl/31/5/local/advertising.pdf; *Advertising*, 31-4 GUT 365 (Apr. 1, 1990), https://gut.bmj.com/content/gutjnl/31/4/local/advertising.pdf; *Advertising*, 31-3 GUT 245 (Mar. 1, 1990), https://gut.bmj.com/content/gutjnl/31/3/local/advertising.pdf.

[105] *Advertising*, 35-9 GUT 1155 (Sept. 1, 1994), https://gut.bmj.com/content/gutjnl/35/9/local/advertising.pdf; *Advertising*, 37-1 GUT 1 (July 1, 1995), https://gut.bmj.com/content/gutjnl/37/1/local/advertising.pdf.



572. And GSK ran the following newspaper ads in 1995 and 1996, which featured narrative accounts of patients suffering from Acid Reflux Disease visiting their doctors and being prescribed Zantac:[106]

[106] BLUEFIELD DAILY TELEGRAPH (Nov. 5, 1995), https://newspaperarchive.com/bluefield-daily-telegraph-nov-05-1995-p-56/ (publication located in Bluefield, WV); ALAMOGORDO DAILY NEWS, (Feb. 25, 1996), https://newspaperarchive.com/alamogordo-daily-news-feb-25-1996-p-40/ (publication located in Alamogordo, NM).

573. From at least 2009-2015, BI represented in Zantac OTC advertisements that the active ingredient ranitidine had been "prescribed by doctors for years to treat millions of patients safely and effectively."[107]

[107] *See, e.g.*, Zantacotc.com (June 8, 2009), https://web.archive.org/web/20090608184215/http://www.zantacotc.com/products/zantac150cool.jsp; Zantacotc.com (May 13, 2013), https://web.archive.org/web/20130513180645/http://www.zantacotc.com/products/zantac150cool.jsp.

574. In 2019, Sanofi made the same representation through its own advertising, which stated that Zantac OTC "has the active ingredient ranitidine, which doctors have prescribed for years to treat millions of patients safely and effectively."[108]

b. Brand-Name Manufacturer Defendants Marketed Zantac OTC as a Safe and Effective Medication to Prevent and Relieve Heartburn Caused by the Consumption of Nitrite- and Nitrate-Rich Foods

575. Brand-Name Manufacturer Defendants misrepresented to the public in print, radio, and television advertisements and on social media that Zantac OTC was safe to be taken for fast heartburn relief before or after consumption of nitrite- and nitrate-rich foods. Brand-Name Manufacturer Defendants wholly omitted any information from their advertisements that disclosed the serious health risks posed by use or ingestion of Ranitidine-Containing Products – particularly when taken with nitrite- and nitrate-rich foods – despite knowing that Ranitidine-Containing

[108] Zantacotc.com (Feb. 7, 2019), https://web.archive.org/web/20190207202602/https://www.zantacotc.com/heartburn-relief.html.

Products presented a dangerous and unreasonable risk of injury to its end-users through elevated levels of NDMA.

576. For instance, in 2006, Pfizer ran a television advertisement depicting a man and a woman standing outside a BBQ restaurant, with the man promising the woman that taking Zantac OTC before their meal will prevent her heartburn. This advertisement also represented that Zantac OTC taken after a meal can provide fast-acting heartburn relief.

577. In 2009, BI ran a television advertisement depicting a woman drinking coffee and eating a burrito at work, with a voiceover saying: "Chug that coffee. Gulp that burrito. No matter what life throws at you, you can take the heat. Until it turns into heartburn. Good thing you've got what it takes to beat that heat too. Zantac – it's strong. Just one pill can knock out the burn." In 2011, BI also ran a similar television advertisement depicting a man drinking coffee and eating a hotdog, with a voiceover saying: "Chug that java. Down that dog. No matter what life throws at you, you can take the heat. Until it turns into heartburn. Good thing you've got what it takes to beat that heat too. Zantac – it's strong. Just one pill can knock out the burn."

578. In 2010, BI advertised its "Zantac Beat the Heat Sweepstakes," through both radio[109] and print advertisements. BI's newspaper advertisements included the slogan, "Zantac BEAT THAT HEARTBURN HEAT," and featured the host of the television program, *Man v. Food*, holding a box of Zantac OTC in front of a basket of buffalo chicken wings.[110] Another

[109] BI advertised its "Zantac Beat the Heat Sweepstakes" via radio on at least two occasions: in the Cleveland, Ohio market on May 20, 2010, and in the Chicago, Illinois market on June 30, 2010.

[110] This advertisement was placed in a Cleveland, Ohio newspaper on May 23, 2010.

newspaper advertisement[111] placed in the same year showed a pizza with a frowning face and promised that Zantac products would provide "fast and long-lasting heartburn relief":

579. In 2013, BI announced the introduction of Captain Zantac, "the new face of [the] ZANTAC Brand."[112] Captain Zantac was a miniature animated fire captain who was used in television, radio, and print advertisements.

[111] This advertisement was placed in newspapers in Atlanta, Georgia and Dallas, Texas on November 10, 2010.

[112] Boehringer Ingelheim Pharmaceuticals, Inc., *Zantac® Launches Innovative Integrated Marketing Campaign to Educate Consumers on Heartburn Relief*, CISION PR NEWSWIRE (Sept. 9, 2013, 11:00 ET), https://www.prnewswire.com/news-releases/zantac-launches-innovative-integrated-marketing-campaign-to-educate-consumers-on-heartburn-relief-222968201.html (last accessed June 20, 2020).

580. In discussing the introduction of Captain Zantac, the first animated character to appear in advertising for OTC heartburn medication, Ross Ullman, the Executive Director of Marketing for BI stated the use of an "iconic" character serves as a "persuasive and memorable platform to cut through the heartburn advertising clutter and educate consumers on which heartburn solutions are really right for them."[113] The stated goal for Captain Zantac was to "help heartburn sufferers understand that . . . ZANTAC rushes relief in as little as 30 minutes."[114]

581. In addition to a prolific presence on television airways, Captain Zantac was also used and displayed in retail pharmacies to draw attention to Zantac:

582. Like the radio and print advertisements involving the Zantac Heartburn Challenges, Captain Zantac also encouraged consumers to take Zantac with food:[115]

[113] *Id.*

[114] *Id.*

[115] @ZantacOTC, TWITTER (July 23, 2016), https://twitter.com/ZantacOTC/status/756858939732439041/photo/1.

583. From at least 2017-2019, Sanofi continued marketing Zantac as a safe and effective treatment medication for the treatment of heartburn caused by consuming nitrite- and nitrate-rich foods.

584. In furtherance of these marketing goals, Sanofi retained ownership of the Captain Zantac trademark[116] on or around February 2018 and continued to use Captain Zantac in television, radio, and print advertisements.

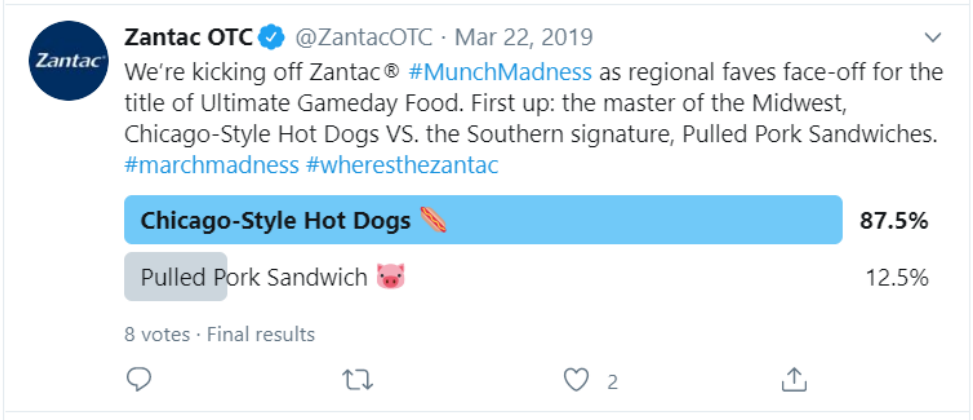
585. Captain Zantac (or "Cap Z" as he was colloquially referred to in materials created and used by Sanofi) also maintained an active social media presence, tweeting frequently[117] and inducing consumers to interact with the Twitter account through the use of free giveaways and sweepstakes.

[116] Justia, https://trademarks.justia.com/864/26/captain-86426387.html (last visited June 20, 2020).

[117] @ZantacOTC, TWITTER (Sept. 3, 2019), https://twitter.com/.

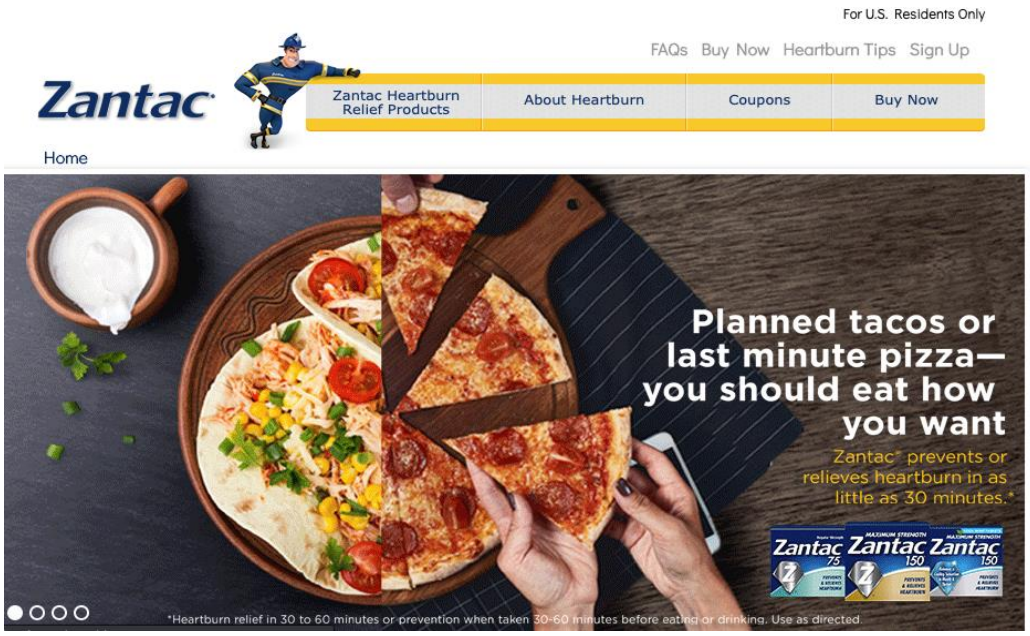
586. Cap Z's Twitter presence also offered "#ZanHacks" which were tips that he offered to consumers to induce them to take Zantac with food consumption.

587. Cap Z likewise encouraged consumers to take Zantac with nitrite-rich foods, through the use of social media engagement campaigns.



588. Captain Zantac was also integrated into Sanofi's other consumer marketing piece, a branded website called zantacotc.com, which also served to promote the use of Zantac with nitrate rich foods.

589. For example, Sanofi presented the following on zantacotc.com:[118]



[118] Zantacotc.com (Apr. 5, 2019), https://web.archive.org/web/20190405064719/https:/www.zantacotc.com/; Zantacotc.com (Feb. 7, 2019), https://web.archive.org/web/20190207202602/https://www.zantacotc.com/heartburn-relief.html.

590. From at least 2018-2019, Sanofi ran a television ad campaign that featured the slogan, "Eat your way. Treat your way." One of these television advertisements depicted a family enjoying "taco night" and a man suffering from heartburn after unexpectedly having pizza for lunch. Another television advertisement attached to this campaign showed a man and woman at a cookout both rubbing their stomachs in pain in front of a plate of hamburgers, while a voiceover said, "Zantac works in as little as 30 minutes. Eat your way. Treat your way."

591. Indeed, Brand-Name Manufacturer Defendants ran myriad television, print, radio, and internet ads that communicated similarly misleading messages:

First Date	Brand-Name Manufacturer Defendant	Advertising Medium	Title	Market
04/17/2006	Pfizer	Television	MAN OFFERS PEOPLE FAST RELIEF	Salt Lake City, UT
04/28/2006	Pfizer	Radio	Family Controls Heartburn	Los Angeles, CA
01/01/2008	BI	Radio	Woman Calls It Here It Comes Again	Tampa, FL
01/01/2008	BI	Radio	Woman Calls It Here It Comes Again	New York, NY
01/01/2008	BI	Radio	Heartburn Isn't Funny	Washington, D.C.
01/01/2008	BI	Radio	Woman Calls It Here It Comes Again	Baltimore, MD
01/01/2008	BI	Radio	Man Goes to Bed at Nine	Phoenix, AZ
01/03/2008	BI	Radio	Heartburn Isn't Funny!	Atlanta, GA
01/03/2008	BI	Radio	Heartburn! Attack It. Zantac	Tampa, FL
01/03/2008	BI	Radio	I Will Go to Bed at Nine	Los Angeles, CA
01/04/2008	BI	Radio	Heartburn! Attack It. Zantac	Orlando, FL
01/04/2008	BI	Radio	Take Zantac to Relieve Heartburn	Boston, MA
01/07/2008	BI	Radio	Heartburn! Attack It. Zantac	Los Angeles, CA
01/09/2008	BI	Radio	The Embarrassing Part of Heartburn	Los Angeles, CA
12/16-17/2008	BI	Newspaper	Because these days, breakfast while reading the	Miami, FL

First Date	Brand-Name Manufacturer Defendant	Advertising Medium	Title	Market
			morning paper may be all it takes to trigger heartburn.	
04/08/2009	BI	Radio	Heartburn Won't Slow You Down	San Francisco, CA
10/12/2009	BI	Television	Woman Gets Heartburn at Work	USA
11/17/2009	BI	Television	Woman Gets Heartburn at Work	St. Louis, MO
05/23/2010	BI	Newspaper	BEAT THAT HEARTBURN HEAT.	Cleveland, OH
09/05/2010	BI	Television	Beat that Heartburn Heat	Orlando, FL
11/10/2010	BI	Newspaper	Can't find your usual heartburn remedy?	Atlanta, GA Dallas, TX
08/22/2011	BI	Television	Fast Relief in a Short Time	USA
01/12/2015	BI	Magazine	CAPTAIN Zantac IN HEARTBURN RESCUE	USA
03/02/2015	BI	Magazine	CAPTAIN Zantac IN HEARTBURN RESCUE	ESPN
09/13/2015	BI	Television	Zantac Heartburn Challenge	LMN
09/27/2015	BI	Online Video	Take the Challenge	YAHOOENT Video
11/14/2015	BI	Television	Get Faster Relief	LMN
12/09/2016	BI	Television	Get the Fast Heartburn Relief	Denver, CO
02/05/2017	Sanofi	Television	Fast Heartburn Relief	FNEW
03/07/2017	Sanofi	Online Video	Releases Cooling Sensation in Mouth and Throat	Answers.com Video
06/26/2017	Sanofi	Television	Better for Heartburn Relief	Portland, OR
11/13/2017	Sanofi	Television	Best Relief from Heartburn	TVL
04/09/2018	Sanofi	Television	The Fast Relief	San Francisco, CA
07/03/2018	Sanofi	Online Video	No Mess Fast Relief Heartburn Night	TLC.com Video
07/27/2018	Sanofi	Television	Best Relief from Heartburn	Raleigh, NC
03/14/2019	Sanofi	Online Video	The Fast Relief	Maxpreps.com Video
04/08/2019	Sanofi	Television	Prevent or Relief Heartburn	San Francisco, CA
04/08/2019	Sanofi	Online Video	Man & Boy Are Eating Taco in the Dining Table	Xfinity.com Video
04/21/2019	Sanofi	Television	Relieves It Fast	Atlanta, GA

c. BI and Sanofi Utilized Ostensibly Unbranded Marketing Tactics to Promtoe Zantac as Safe

592. BI and Sanofi also misrepresented via an ostensibly unbranded website and Defendant-funded journal articles purporting to offer neutral scientific evidence that Zantac had no safety concerns, or any known clinically significant integrations, that were present with other commonly prescribed drugs, without disclosing the instability of ranitidine – the active ingredient in Zantac.

593. On November 15, 2015, BI bought/registered the domain name rethinkppis.com, which transferred to Sanofi on February 24, 2017. The unbranded website included data connecting Proton Pump Inhibitors ("PPIs"), a different category of drugs in the antacid market, with increased cardiovascular risks, kidney disease, low magnesium, bone fractures, and gut bacteria, and noted that H_2 blockers were not proven to be associated with those same risks:

> **PPIs have other safety concerns H_2 blockers do not**
>
> - H_2 blockers like non-prescription Zantac® have no long-term safety concerns when used as directed or no known clinically significant interactions with other commonly prescribed drugs people may be taking, unlike PPIs such as Nexium®.
> - Unlike PPIs, increased risk of fractures of the hip, wrist, and spine have not been reported in clinical studies with H_2 blockers.[119]

594. Neither BI or Sanofi contemporaneously, or at any time, disclosed on the rethinkppis.com website the dangers of NDMA or that the active ingredient in Zantac – ranitidine – was unstable and broke down in to cancer-causing NDMA.

[119] *RethinkPPIs.com* (Feb. 19, 2016), https://web.archive.org/web/20160219011903/http://www.rethinkppis.com/.

D. Defendants' Ranitidine-Containing Products Are Misbranded and Adulterated Because They Contain Biologically Relevant Levels of NDMA

595. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[120]

596. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[121]

597. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[122]

598. Among the ways a drug may be adulterated and/or misbranded are:

(a) "[I]f it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess[.]"[123]

(b) "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium."[124]

(c) "If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[125]

599. A drug is misbranded:

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[120] 21 U.S.C. §331(g).

[121] 21 U.S.C. §331(a).

[122] 21 U.S.C. §331(c).

[123] 21 U.S.C. §351(a)(2)(B).

[124] 21 U.S.C. §351(b).

[125] 21 U.S.C. §351(d).

(a) "If its labeling is false or misleading in any particular."[126]

(b) "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[127]

(c) If the labeling does not contain, among other things, "the proportion of each active ingredient[.]"[128]

(d) "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users[.]"[129]

(e) "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[130]

(f) "[I]f it is an imitation of another drug[.]"[131]

(g) "[I]f it is offered for sale under the name of another drug."[132]

(h) "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[133]

(i) If the drug is advertised incorrectly in any manner.[134]

(j) If the drug's "packaging or labeling is in violation of an applicable regulation[.]"[135]

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126 21 U.S.C. §352(a)(1).

127 21 U.S.C. §352(c).

128 21 U.S.C. §352(e)(1)(A)(ii).

129 21 U.S.C. §352(f).

130 21 U.S.C. §352(g).

131 21 U.S.C. §352(i)(2).

132 21 U.S.C. §352(i)(3).

133 21 U.S.C. §352(j).

134 21 U.S.C. §352(n).

135 21 U.S.C. §352(p).

600. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[136]

601. Because Defendants did not disclose NDMA as an ingredient in the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

602. Because Defendants did not disclose the proper directions for storage of the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

603. Because Defendants did not disclose the proper directions for expiration of the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

604. It is unlawful to introduce a misbranded drug into interstate commerce.[137] Thus, the Ranitidine-Containing Products purchased and/or used by Plaintiffs and the Class were unlawfully distributed and sold.

E. Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants Concealed the Presence of NDMA in Ranitidine-Containing Products from Consumers and the FDA

605. During the time that Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants manufactured and sold Ranitidine-Containing Products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe NDMA.[138] Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants concealed and failed to disclose this risk to consumers – including through product labels, advertisements, or through any other means – and they concealed and failed to report these risks to the FDA, which

[136] 21 C.F.R. §§201.6, 201.10.

[137] 21 U.S.C. §331(a).

[138] *See supra*, ¶¶491-537.

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.

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

607. 21 C.F.R. §314.81(b)(2)(v) provides:

> The manufacturer's annual report also must 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.

608. Brand-Name Manufacturer Defendants and Generic 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.

609. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in scientific literature such that Defendants, consistent with their heightened obligations to ensure the safety of their products, should have known about the NDMA risks associated with ranitidine consumption.

610. Further, Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants never conducted or provided the relevant studies to the FDA, nor did they present the

FDA with a proposed disclosure noting the link between ranitidine and NDMA. Accordingly, because Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants never properly disclosed the NDMA risk 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 guidelines.

611. Defendants had a duty to disclose the NDMA risks in their Ranitidine-Containing Products. They had superior knowledge of material facts that consumers like Plaintiffs and Class members could not discover through ordinary diligence. And by affirmatively representing on labels, in advertisements, and elsewhere that Ranitidine-Containing Products were safe, Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants were obligated to say disclose enough about the inherent risks of the Ranitidine-Containing Products to prevent their partial representations from misleading consumers like Plaintiffs and Class members.

612. 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 Brand-Name Manufacturer Defendant or Generic 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 much sooner, which would have prevented the widespread harm that Defendants' Ranitidine-Containing Products caused to Plaintiffs and the Class in the interim.

F. Defendants Made and Breached Warranties to Plaintiffs and Class Members

1. Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Repackager Defendants Made and Breached Warranties to Plaintiffs and Class Members

613. Each Brand-Name Manufacturer Defendant's, Generic Manufacturer Defendant's, and Repackager Defendant's Ranitidine-Containing Product includes an FDA-approved label that made representations and express or implied warranties to consumers, including Plaintiffs and Class members, that these Defendants' products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded.

614. In addition, each Brand-Name Manufacturer Defendant, Generic Manufacturer Defendant, and Repackager Defendant affirmatively misrepresented and warranted to Plaintiffs, Class members, and physicians, through their websites, brochures, social media, and other marketing or informational materials, that their Ranitidine-Containing Products complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

a. BI

615. In its Global Code of Conduct, BI touts that "integrity is 'part of our DNA'"[139] and states:

> Ensuring a positive benefit-risk balance of our products is of critical importance to us. We monitor our products to ensure the level of quality and safety expected by our customers and regulators worldwide.
>
> * * *

[139] Boehringer Ingelheim, *With Integrity and Passion, Our Global Code of Conduct*, at 1, https://www.boehringer-ingelheim.com.br/sites/br/files/coc_bi_coc_26072018_2.pdf (last visited June 20, 2020).

> We consider quality, including all its integral compliance aspects, as indispensable in researching, developing and providing safe and efficacious products for our patients.
>
> * * *
>
> We provide accurate, fair and balanced information about our products, and do not engage in activities that inappropriately benefit or influence our customers or stakeholders. We strictly follow applicable transparency and disclosure standards required by law, regulations and codes of practice.[140]

b. GSK

616. GSK promises to "do the right thing" for patients and consumers and to "strive for the highest quality."[141] In its Code of Conduct, GSK states:

> We put [patients' and consumers'] safety first, provide them with clear, up-to-date information and promote our products appropriately and ethically.
>
> * * *
>
> Our promotional activities and materials conform to high ethical, medical and scientific standards. They are legal, industry-compliant and evidence based.
>
> * * *
>
> We provide complete, up-to-date and evidence based product information to healthcare professionals and consumers, wherever they are in the world.
>
> * * *
>
> We strive to assure the safety, quality and efficacy of our products for our patients and consumers by ensuring that our procedures comply with Good Practice regulations.[142]

617. Throughout the almost four decades that Zantac has been marketed and sold in the United States by GSK, GSK has frequently represented itself as a company committed to

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[140] *Id.* at 4-5.

[141] GSK, *Living Our Values and Expectations, Our Code of Conduct*, at 11 https://www.gsk.com/media/4800/english-code-of-conduct.pdf (last visited June 20, 2020).

[142] *Id.* at 11-12.

manufacturing quality, and safe, products, repeatedly touting that its primary focus was to "improve the quality of human life." [143] GSK touted oversight of "product quality across the supply chain, from suppliers and third party manufacturers through manufacturing to the supply operations that deliver products into the market."[144]

618. This mantra was repeated throughout their annual reports when GSK represented that they were:

- "generat[ing] the right information about" about products to provide to TPPs including information about "safety, efficacy and quality" (2000)[145]
- "delivering quality products to markets around the world" (2001)[146]
- "improving productivity in both quality and quantity" (2002)[147]
- "developing more high quality compounds than ever before" (2003)[148]
- focusing on securing a supply of "high quality products" that are "best in class" while being at the "leading edge [o]f practices and performances" (2004)[149]

[143] GSK, *2007 Annual Report*, at 1 (2007), http://www.annualreports.com/HostedData/AnnualReportArchive/g/LSE_GSK_2007.pdf.

[144] *Id.* at 26.

[145] GSK, *2000 Annual Report*, at 20 (2000), https://www.gsk.com/media/4698/annual-report-2000.pdf.

[146] GSK, *2001 Annual Report*, at 13 (2001), https://www.gsk.com/media/2660/annual-review-2001.pdf.

[147] GSK, *2002 Annual Report*, at 20 (2002), https://www.sec.gov/Archives/edgar/data/1131399/000102123103000405/gsk_report.pdf.

[148] GSK, 2003 *Annual Report*, at 3 (2003), https://www.gsk.com/media/2669/annual-report-2003.pdf.

[149] GSK, *2004 Annual Report*, at 13 (2004), https://www.sec.gov/Archives/edgar/data/1131399/000102123103000405/gsk_report.pdf.

- having "[s]ophisticated quality assurance and quality control procedures . . . in place" (2005)[150]
- having a "secure source of supply of high quality products" (2006)[151]
- overseeing "product quality across the supply chain, from suppliers and third party manufacturers through manufacturing to the supply operations that deliver products into the market" (2007)[152]

619. However, a 2010 Settlement with the Department of Justice laid bare the truth of GSK's operations, which included a slew of compliance related issues, such as the distribution of ointments that contained microorganisms, sale of drugs that contained no active ingredient, contamination of sterile drugs, rendering them non-sterile, and the like.[153]

620. In a statement from July 2012, newly minted GSK CEO Sir Andrew Witty conceded that GSK had made "mistakes" and that there had been employees who had "engaged in misconduct," but that, as of 2012, GSK had a "clear priority to ingrain a culture of putting patients first, acting transparently, respecting people inside and outside the organization and displaying integrity in everything we do."[154]

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[150] GSK, *2005 Annual Report*, at 9 (2005), https://www.gsk.com/media/2676/annual-report-2005.pdf.

[151] GSK, *2006 Annual Report*, at 21 (2006), https://www.gsk.com/media/2679/annual-report-2006.pdf.

[152] GSK, *2007 Annual Report*, supra, n. 143, at 26.

[153] Department of Justice & GSK, *Settlement Agreement*, JUSTICE.GOV (Oct. 26, 2010), https://www.justice.gov/archive/usao/ma/news/2010/October/GSK%20Settlement%20Agreement10_26.pdf.

[154] GSK, *GlaxoSmithKline Concludes Previously Announced Agreement in Principle to Resolve Multiple Investigations with US Government and Numerous States* (July 2, 2012), https://www.gsk.com/en-gb/media/press-releases/glaxosmithkline-concludes-previously-announced-agreement-in-principle-to-resolve-multiple-investigations-with-us-government-and-numerous-states/.

c. Pfizer

621. In its summary of policies on business conduct, Pfizer affirms its understanding that "integrity is . . . accountability" and states:[155]

> Pfizer is subject to many rules and regulations designed to protect patients and consumers, improve the quality of medicines . . . . We are committed to following the laws and regulatory requirements that govern our business, including the development, manufacturing, distribution, marketing, . . . sale and promotion of our products.
>
> * * *
>
> We operate a comprehensive and robust quality management system designed to ensure the production and supply of quality products. We are committed to ensuring that our products are manufactured and supplied to high standards of quality. We are also committed to conducting our manufacturing operations in compliance with applicable regulatory requirements, good manufacturing practices (GMP) and our own internal rigorous quality standards. We also require that our suppliers and partners adhere to high standards, and we conduct audits and oversight of our supply chain.[156]

d. Sanofi

622. Sanofi's CEO's opening missive in the Sanofi Code of Ethics states that "[i]ntegrity is a commitment that must guide our behaviors beyond mere compliance with law and regulation, driving us to make the right choice when facing any situation."[157] Sanofi further states that it is "keen to account for" and anticipate patient's expectations and that it "communicates transparently about its products and ensures that information about the efficacy and safety of its products is continuously monitored and updated throughout their lifecycle."[158]

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[155] Pfizer, *The Blue Book Summary of Pfizer Policies on Business Conduct*, at 12 (2009), https://www.pfizer.com/sites/default/files/investors/corporate/blue_book_english.pdf.

[156] *Id.* at 12, 17.

[157] Sanofi, *Sanofi Code of Ethics, Our Commitment to Acting with Integrity*, http://www.codeofethics.sanofi/EN (last visited June 13, 2020).

[158] *Id.*

e. Amneal

623. Amneal states it "produce[s] quality generic, specialty and biosimilar medicines."[159] Amneal proudly proclaims that its "quality culture is one of the core pillars of our success."[160]

624. Amneal further touts its success in "consistently meet[ing] or exceed[ing] quality, industry and global regulatory standards."[161]

625. As part of their corporate "Purpose and Commitment," Amneal sets "a high bar for our products, pipeline, operations and service – always going the extra mile to exceed expectations and reliably execute in everything we do . . . because patients' lives depend on it."[162]

626. Amneal's SEC filings clearly acknowledge manufacturers are "required to comply with cGMP standards at all times during the production and processing of pharmaceuticals, and the FDA may inspect the manufacturer's sites at any time to ensure compliance."[163] Amneal further recognizes "[its] products must be made in a manner consistent with cGMP" in the United States and around the globe and maintains it is "committed to continuing to improve [its] quality control and manufacturing practices."[164]

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[159] *Our Portfolio*, AMNEAL, https://www.amneal.com/products/our-portfolio/ (last visited June 17, 2020).

[160] *Quality*, AMNEAL, https://www.amneal.com/products/quality/ (last visited June 17, 2020).

[161] *Id.*

[162] *Our Purpose & Commitments*, AMNEAL, https://www.amneal.com/about/our-purpose-commitments/ (last visited June 17, 2020).

[163] Amneal Pharmaceuticals, Inc., *Annual Report (Form 10-K)*, at 8 (Mar. 2, 2020), http://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_AMRX_2019.pdf.

[164] *Id.* at 16.

f. Aurobindo

627. Aurobindo insists they are "committed to quality and safety."[165]

628. Further, Aurobindo "[a]spire[s] to . . . emerge as a leading global player in high quality, innovative specialty generic formulations."[166]

629. Aurobindo asserts the following "Core Strengths" in "Formulations":

- Vertically integrated operations from conception to commercialization.
- Large manufacturing capabilities for a diversified product portfolio.
- Efficient regulatory affairs team ensuring market compliance.
- Dedicated R&D setup for finished dosages and active ingredients.
- Technology and expertise for specialty formulations.[167]

630. As part of Aurobindo's "Research and Development" commitment, Aurobindo maintains that it meets federal requirements, and is "focused on the areas of organic synthesis, analytical research, dosage form development, pharmacology, bio-equivalence studies and drug delivery systems."[168]

631. Aurobindo further asserts a four-point "instrumentation and analytical knowledge base" that the company implements:[169]

- complete impurity profiling in all products developed;
- development of analytical methods and specifications from raw materials, to non-compendial finished products;

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[165] AUROBINDO, https://www.aurobindo.com/ (last visited June 17, 2020).

[166] *Formulations*, AUROBINDO, https://www.aurobindo.com/about-us/business-units/formulations/ (last visited June 17, 2020).

[167] *Id.*

[168] *Id.*

[169] *Id.*

- in-house synthesis of reagents for analyzing organolithiums and noble metals; and
- accelerated and real-time stability studies.

g. Dr. Reddy's

632. Dr. Reddy's asserts that its "focus on quality helps ensure product safety and efficacy."[170]

633. As part of Dr. Reddy's manufacturing of generic drugs, Dr. Reddy's claims it "focuses on continual improvement aimed at optimizing processes and eliminating non-value-adding efforts in production. These efforts are primarily directed towards reducing variability in process and product quality characteristics."[171]

634. In order to "achieve" their "Quality Management System," Dr. Reddy's insists on the following four-step process:[172]

- Adopt Quality by Design (QbD) approach in Manufacturing and clearly identify sources of variability and minimize them on an ongoing basis.
- Be right the first time. Identify and eliminate defects. Improve efficiency.
- Undertake "risk-based" approach to manufacturing and mitigate risks wherever they are likely to impact quality
- Develop transparency in all areas of operations and build robust quality culture across the organization.

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[170] *Quality: World Class Medicines for Everyone*, DR. REDDY'S, https://www.drreddys.com/our-products/quality/ (last visited June 17, 2020).

[171] *Id.*

[172] *Id.*

h. Glenmark

635. Glenmark USA claims to be a "global leader in the development and commercialization of generic drugs of the highest quality and value."[173]

636. As part of their "Operations," Glenmark asserts "[our] dedicated employees and state-of-the-art manufacturing centers help make our vision a reality . . . In a highly regulated environment, where quality and precision are critical, our manufacturing processes are as rigorous as our scientific research. Our state-of-the-art global facilities include all the processes needed to manufacture safe products for our consumers."[174]

i. Lannett

637. Lannett's "generic pharmaceutical products have consistently met the highest standards, and [its] track record for safety and quality is nearly unmatched."[175]

638. Lannett maintains that "[c]ustomers may rest assured that generic pharmaceuticals are produced with the same active ingredients and attention to quality as branded versions."[176]

j. Perrigo

639. PerrigoPerrigo proclaims to sell and manufacture quality, affordable "self-care" products that "consumers trust everywhere they are sold."[177]

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[173] *Generics*, GLENMARK, https://glenmarkpharma-us.com/products/generics/ (last visited June 17, 2020).

[174] *Operations*, GLENMARK, https://glenmarkpharma-us.com/operations/ (last visited June 17, 2020).

[175] *We Care About Affordable Medication*, LANNETT, https://www.lannett.com/approach/ (last visited June 17, 2020).

[176] *FAQ*, LANNETT, https://www.lannett.com/patient-resources/faq/ (last visited June 17, 2020).

[177] PERRIGO, https://www.perrigo.com/ (last visited June 21, 2020).

640. Perrigo describes its "world-class supply chain network" that has a "commitment to quality that cannot be limited to regulatory requirements but must be imbedded into our culture."[178]

641. However, inspections carried out for over the last decade indicate that Perrigo routinely failed to even meet the baseline regulatory obligations required of it to sell and market drugs in the United. States.

642. In 2006, an inspection of Perrigo's Bronx facility uncovered discrepancies between the Standard Operation Procedures ("SOPs") for stability testing of products, and what was actually being done in practice. For example, the FDA inspector noted that the specification results for environmental chambers meant to test drugs in different heat and humidity conditions (to see whether and how quickly the drug were to degrade), did not document humidity results, and did not investigate Out-of-Specification ("OOS") findings.[179]

643. In 2006, during a 39-day inspection of Perrigo's Allegan, Michigan facility, the FDA noted that Perrigo had received complaints related to degradation issues for one of its products (the identify of which is redacted), and finds that there was no stability data to support the 36-month expiration date assigned to the package.[180]

644. Perrigo, obviously not heeding any of the previous warnings, was cited yet again during an even longer 54-day inspection of its Allegan facility for failing to investigate any OOS results for the stability of their products, resulting in the recall of the products because Perrigo

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[178] *Id.*

[179] FDA Form 483, Perrigo Inspection (Aug. 31, 2006).

[180] FDA Form 483, Perrigo Inspection (Nov. 7, 2006).

could no longer support their labeled expiration dates.[181] Even more damningly, the FDA found that results of stability testing were not used at all in "determining expiration dates."[182]

645. As recently as 2019, the FDA cited Perrigo for unacceptable manufacturing practices, including shredding batch production records, unacceptable storage of raw materials in a manner that "creates a potential for mix-up," and storing samples of drug product in a manner that "creates a potential for mix-up."[183]

k. Sandoz

646. Novartis insists that "[q]uality is a key priority in every aspect of our work . . . We are committed to giving back more to society than we take. This makes it imperative that we meet and exceed regulatory expectations, embracing the highest standards of quality and integrity in our work, and ensuring that our decisions are guided always by what's best for our patients."[184]

647. With respect to their generic manufacturing subsidiary, Sandoz, the company proclaims that they "deliver the highest quality products" and that the "Sandoz brand is a seal of quality." [185]

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[181] FDA Form 483, Perrigo Inspection (Nov. 7, 2008).

[182] *Id.*

[183] FDA Form 483, Perrigo Inspection (Oct. 22, 2019).

[184] *Novartis Quality Commitment*, NOVARTIS, https://www.novartis.com/our-company/our-culture-and-values/novartis-quality-commitment (last visited June 17, 2020).

[185] *Innovation, Quality and Supply*, SANDOZ, https://www.sandoz.com/about-us/who-we-are/innovation-quality-and-supply (last visited June 18, 2020).

l. Strides

648. Strides proudly asserts its work in "Pharma Generics-United States" by insisting its "presence" in the United States "enhances [their] ability to reach a larger base of customers and patients in need of quality treatment options."[186]

649. Strides is "led and driven by its expertise in Research and Development."[187]

650. Strides also brags about its resources, describing its "200 plus scientists, the R&D team offers solutions across the entire product development value chain including strategic sourcing, IP management, formulation development, analytical method development and validation . . . bio-equivalence, toxicological studies, packaging development and global regulatory submissions."[188]

m. Teva

651. Teva proudly "strive[s] to deliver quality medicines to patients around the world with integrity and ethical business practices."[189]

652. Under its "Generic FAQs" webpage, Teva responds to the question "are generic drugs as safe" by maintaining that their generic drugs "meets . . . quality standards."[190]

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[186] *Pharma Generics - United States*, STRIDES, http://www.strides.com/pharma-united-states.html (last visited June 17, 2020).

[187] *R&D*, STRIDES, http://www.strides.com/corporate-rd.html (last visited June 17, 2020).

[188] *Id.*

[189] *Generic Medicines*, TEVA, https://www.tevapharm.com/product-focus/generics/ (last visited June 17, 2020).

[190] *Id.*

653. Teva proudly proclaims it is "one of the few global pharmaceutical companies that has integrated scientific expertise across generic and specialty (branded) R&D capabilities."[191]

654. Teva goes on to insist its "world-class scientists and doctors focus on being first to market, while ensuring the quality and affordability of our treatments and medicines. Teva's R&D group has an exceptional track record in translating early drug opportunities into clinically-proven drug candidates by using cutting edge research in facilities that are fully equipped to support both good laboratory practice (GLP) and current good manufacturing practice (cGMP) regulations."[192]

655. Under the "Quality Products" webpage, Teva asserts the following:

> We validate and continually monitor our manufacturing processes to ensure they perform as expected. Each of our products is tested to confirm compliance to Teva's quality specifications and compliance standards. Because Teva is vertically integrated, we supply a substantial amount of our own active pharmaceutical ingredients. That allows us to closely control product quality . . . As a result, we have an enviable record of Current Good Manufacturing Practice (cGMP) compliance.[193]

n. Wockhardt

656. Wockhardt claims it is a global pharmaceutical and biotechnology organization "providing affordable, high quality medicines for a healthier world."[194]

657. Wockhardt achieves its "success" having built an "international manufacturing footprint" that has earned the reputation of a "world-class manufacturer."[195]

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[191] *Generics R&D*, TEVA, https://www.tevapharm.com/product-focus/research/generics-r-d/ (last visited June 17, 2020).

[192] *Id.*

[193] *Producing Quality Products that Improve Lives*, TEVA, https://www.tevapharm.com/product-focus/our-quality/ (last visited June 17, 2020).

[194] *Manufacturing*, WOCKHARDT, http://www.wockhardt.com/who-we-are/manufacturing.aspx (last visited June 17, 2020).

[195] *Id.*

658. According to Wockhardt, its "core business is innovation."[196] The website goes on to proudly proclaim that it "Spearhead[s] Research & Development" and "uses science and technology to develop medicines and other products that improve the quality of millions [of] people's lives through better health."[197]

659. Wockhardt further asserts it "has proved its technical excellence by developing patented modified release formulations and recombinant biotechnology products. It has a multi-disciplinary R&D programme with more than 607 scientists, including over 80 doctorates, in the areas of . . . Pharmaceutical Research" and "Active Pharmaceutical Ingredients" Research."[198]

660. The presence of NDMA in Defendants' Ranitidine-Containing Products results in the Ranitidine-Containing Products containing an ingredient that is not also listed on each Defendant's FDA-approved label, breaching warranties arising from such labels, including Defendants' express warranty of compliance. Defendants willfully, recklessly, or negligently failed to ensure their products' labels and other advertising or marketing statements accurately conveyed information about their products.

661. Defendants have also impliedly warranted that their Ranitidine-Containing Products were merchantable and fit for their ordinary purposes.

662. The presence of NDMA in Brand-Name Manufacturer Defendants', Generic Manufacturer Defendants', and Repackager Defendants' Ranitidine-Containing Products resulted in the Ranitidine-Containing Products containing an ingredient that is not also listed on each

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[196] *Who We Are: Overview*, WOCKHARDT, http://www.wockhardt.com/who-we-are/overview.aspx (last visited June 17, 2020).

[197] *Id.*

[198] *Id.*

Defendant's FDA-approved label, breaching warranties arising from such labels, and each Defendants' express warranty of compliance. Each Brand-Name Manufacturer Defendant, Generic Manufacturer Defendant, and Repackager Defendant willfully, recklessly, or negligently failed to ensure their products' labels and other advertising or marketing statements accurately conveyed information about their products.

663. At all relevant times, Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Repackager Defendants also impliedly warranted that their Ranitidine-Containing Products were merchantable and fit for their ordinary purposes.

664. Due to its status as a probable human carcinogen as recognized by both the IARC and the EPA, NDMA is not an FDA-approved ingredient. The presence of NDMA makes these Defendants' Ranitidine-Containing Products not merchantable and/or unfit for their ordinary purposes. Thus, Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Repackager Defendants breached implied warranties to Plaintiffs and the Class.

665. Further, by selling drugs in the stream of commerce, each Repackager Defendant warranted that the generic drugs they sold were the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. And each Repackager Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

666. For these and other reasons, Brand-Name Manufacturer Defendants', Generic Manufacturer Defendants', and Repackager Defendants' Ranitidine-Containing Products are therefore adulterated and/or misbranded, and it was illegal for Brand-Name Manufacturer

Defendants, Generic Manufacturer Defendants, and Repackager Defendants to have introduced Ranitidine-Containing Products into commerce in the United States.[199]

2. Retailer Defendants Breached Warranties to Plaintiffs and Class Members

667. Retail pharmacies are where consumers like Plaintiffs and Class members purchase OTC Ranitidine-Containing Products and purchase and fill prescriptions for prescription-strength Ranitidine-Containing Products. As a result, Retailer Defendants and consumers are in direct privity of contract. With each sale of a Ranitidine-Containing Product, Retailer Defendants impliedly warranted to Plaintiffs and Class members that the products being sold to them were merchantable and/or fit for their ordinary uses.

668. In addition, by selling pharmaceutical drugs in the stream of commerce, each Retailer Defendant warranted to Plaintiffs and Class members that the Ranitidine-Containing Products they sold were safe and effective.

669. Further, each Retailer Defendant was obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

670. For the reasons alleged herein, Retailer Defendants breached their warranties to Plaintiffs and Class members.

3. Distributor Defendants Breached Warranties to Plaintiffs and Class Members

671. Cardinal Health's Standards of Business Conduct state, "We have quality systems in place to ensure that we manufacture, handle, store and distribute products in accordance with

[199] *See* 21 U.S.C. §§331(a), 331(g), 351(a)(2)(B).

applicable legal and regulatory requirements. Every employee is responsible for following our quality processes when working with the products we sell."[200] The Standards also require Cardinal to "[u]nderstand and comply with the policies that cover the manufacture, storage, handling and distribution of products we sell."[201]

672. McKesson's Code of Conduct provides that it only does "[b]usiness [f]airly and with [i]ntegrity."[202] McKesson touts that it "compl[ies] with applicable laws everywhere we do business around the world[,]" and requires action by the company when it is "aware of (or even suspect[s]) illegal or unethical behavior or violations of the Code, other local policies or applicable laws."[203]

673. AmerisourceBergen's Code of Ethics and Business Conduct states that the company shall engage in "[f]air [d]ealing" and will not "take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair dealing practice."[204]

674. Chattem follows the Sanofi Code of Ethics.[205]

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[200] Cardinal Health, *Standards of Business Conduct*, at 30, https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-standards-of-business-conduct-booklet-english.pdf. (last visited June 20, 2020).

[201] *Id.*

[202] McKesson, *Code of Conduct*, at 3, https://www.mckesson.com/Investors/Corporate-Governance/Code-of-Conduct (last visited June 20, 2020).

[203] *Id.* at 1.

[204] AmerisourceBergen, *Code of Ethics and Business Conduct 2019*, at 11 https://s24.q4cdn.com/386340686/files/doc_downloads/policies/ABC_CodeofEthics_2019.pdf (last visited June 20, 2020).

[205] *See* Sanofi, *Code of Ethics and US Supplement*, http://chattem.com/Downloads/Code%20of%20Ethics%20with%20US%20Supplement%20Nov%202011.pdf (last visited June 20, 2020).

675. Further, each Distributor Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

676. Distributor Defendants failed to conform to these representations and warranties and, thus, breached their warranties to Plaintiffs and Class members.

G. Defendants Failed to Comply with Current Good Manufacturing Practices

677. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards.[206]

678. 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.

679. 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.

[206] 21 U.S.C. §351(a)(2)(B).

680. Any drug not manufactured in accordance with cGMPs is deemed "adulterated or misbranded" and may not be distributed or sold in the United States.[207] State common law and statutory law mirror these federal standards.

681. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[208] 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. The 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 withdrawal of Ranitidine-Containing Products altogether.

682. Nothing prevented any of Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, Retailer Defendants, and Distributor Defendants from, on their own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring proper storage and transport conditions. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

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[207] 21 U.S.C. §§331(a), 351(a)(2)(B).

[208] Letter from Janet Woodcock, FDA, to Ramin Najafi, Ph.D., Pres. and CEO, Emery Pharma, (Apr. 1, 2020), https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.

H. Generic Manufacturer Defendants Failed to Comply with Applicable Requirements

683. According to the FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name 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-name version***. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[209]

684. While brand-name 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 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-name version in the following ways:

(a) the active ingredient in the generic medicine is the same as in the brand-name 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-name medicine; and

[209] FDA, *Generic Drugs: Questions & Answers*, https://www.fda.gov/Drugs/ResourcesFor "You/Consumers/QuestionsAnswers/ucm100100.htm (emphasis in original) (last visited June 20, 2020).

(e) the container in which the medicine will be shipped and sold is appropriate.[210]

685. Because the branded manufacturer previously 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.[211]

686. 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."[212]

687. 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 respects.[213] 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[.]"[214]

688. 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

[210] FDA, *Generic Drug Facts*, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm (last visited June 20, 2020).

[211] 21 C.F.R. §314.3.

[212] 21 C.F.R. §211.166(a).

[213] 21 C.F.R. §314.94(a)(8)(iii).

[214] 21 C.F.R. §314.94(a)(8)(iv).

different temperature conditions, and/or requiring the drug to receive different (or no) exposure to light.

I. Repackager Defendants and Distributor Defendants Also Failed in Their Duty to Implement Proper Storage, Handling, and Shipping Conditions

689. During the time that Repackager Defendants and Distributor 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.[215]

690. Repackager Defendants and Distributor Defendants failed to disclose this risk to consumers on the drug's label – or through any other means – and they failed to report these risks to the FDA.

691. The U.S. Pharmacopeial Convention ("USP") sets forth industry standards applicable – in relevant part – to repackagers and distributors. Chapter 1079, entitled, "Good Storage and Shipping Practices," specifies that "[g]ood 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

[215] *See supra* ¶¶491-537.

- Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services[.][216]

692. USP ch. 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."[217]

693. USP ch. 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."[218]

694. Repackager Defendants and Distributor Defendants, as well as Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants, breached their duty to provide proper storage, shipping, and temperature specifications in all of the ways previously mentioned.

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[216] U.S. Pharmacopeial Convention, *Good Storage and Shipping Practices*, ch. 1079, https://pharmacy.ks.gov/docs/default-source/default-document-library/ups-36-good-storage-and-shipping-practices.pdf.

[217] *Id.*

[218] *Id.*

J. The Truth Was Revealed When an Independent Pharmacy and Testing Laboratory Discovered NDMA in Defendants' Ranitidine-Containing Products, Leaving Defendants No Choice but to Recall and Stop Selling

695. On September 9, 2019, Valisure filed its Citizen Petition calling for the recall of all Ranitidine-Containing Products due to exceedingly high levels of NDMA found in Ranitidine-Containing Products. The FDA and European regulators started immediately reviewing the safety of ranitidine with specific focus on the presence of NDMA.[219] This set off a cascade of recalls by Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, Retailer Defendants, and Repackager Defendants.

696. 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.[220]

697. On September 24, 2019, Generic Manufacturer Defendant 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."[221]

698. On September 26, 2019, Generic Manufacturer Apotex and Retailer Defendants Walgreens, Walmart, and Rite Aid voluntarily recalled all of their Ranitidine-Containing Products

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[219] FDA, *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; 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.

[220] FDA, *Statement Alerting Patients and Health Care Professionals*, *supra*, n.219.

[221] FDA, *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.

and removed them from shelves.[222] Apotex issued a statement, noting that "Apotex has learned from the U.S. Food & 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)."[223]

699. On September 28, 2019, Retailer Defendant CVS stated that it would stop selling Zantac and its CVS-repackaged ranitidine out of concern that they might contain a carcinogen.

700. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using an LC-HRMS testing protocol, which "does not use elevated temperatures."[224]

701. On October 8, 2019, Brand-Name Manufacturer Defendant GSK voluntarily recalled all Ranitidine-Containing Products internationally.[225] As part of the recall, GSK publicly

[222] FDA, *FDA Updates and Press Announcements on NDMA in Zantac (Ranitidine), FDA Alerts Health Care Professionals and Patients to Voluntary Recall of Ranitidine Medicines* (Sept. 26, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[223] FDA, *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.

[224] *FDA Provides Update on Testing of Ranitidine for NDMA Impurities*, *supra* n.69.

[225] Medicines and Healthcare products Regulatory Agency, Press Release, *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.

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[.]"[226]

702. On October 18 and 23, 2019, Brand-Name Manufacturer Defendant Sanofi and Generic Manufacturer and Repackager Defendant Dr. Reddy's voluntarily recalled all of their Ranitidine-Containing Products.[227]

703. On October 28, 2019, Generic Manufacturer Defendants Perrigo, Novitium, and Lannett voluntarily recalled all their Ranitidine-Containing Products.[228]

704. In its recall notice, Generic Manufacturer Defendant Perrigo stated, "[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall."[229]

705. Generic Manufacturer Defendant Lannett also acknowledged the presence of NDMA in the API and/or drug product it used to manufacture ranitidine in its recall notice: "Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and

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[226] 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.

[227] FDA, *FDA Releases Additional NDMA Testing Methods and Alerts Healthcare Professionals and Patients to Multiple Voluntary Recalls of Ranitidine (Oct. 23, 2019)*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[228] *Id.*

[229] FDA, *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.

immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA."[230]

706. 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 manufacturers begin to voluntarily recall their Ranitidine-Containing Products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[231]

707. 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.[232] 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. 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 ascorbid acid."[233] If GSK had only heeded Dr. de Flora's advice in 1981, millions of people might have avoided exposure to a known carcinogen and increased risk of developing cancer from ingesting ranitidine.

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[230] FDA, *Lannett Issues Voluntary Nationwide Recall*, *supra* n.74.

[231] FDA, *Laboratory Analysis of Ranitidine and Nizatidine Products* (Nov. 1, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine.

[232] FDA, *Update – FDA Requires Additional Testing of Ranitidine and Nizatidine as Part of Agency's Ongoing Effort to Help Ensure Product Safety for Patients and Consumers* (Dec. 4, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[233] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, *supra* n.3.

708. Between November 1, 2019 and February 27, 2020, the following Generic Manufacturer Defendants and Repackager Defendants recalled their products from the market, citing NDMA concerns: Aurobindo, Amneal, American Health Packaging, GSMS, Precision Dose, Glenmark, Appco, and Denton Pharma.[234]

709. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to label-compliant temperature ranges that would occur during normal transport and storage conditions.

710. 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. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine in temperature-controlled vehicles.

711. In response,[235] 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."[236] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[237] 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

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234 FDA, *FDA Updates and Press Announcements*, *supra* n.69.

235 Letter from Janet Woodcock, *supra* n.208.

236 *Id.* at 5 (citing 21 C.F.R. §7.40(a)).

237 *Id.*

risk."[238] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[239]

712. 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 NDMA levels were higher as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any ranitidine-containing product could remain stable through its labeled expiration date. Consequently, the FDA withdrew the products from the market. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

713. 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.[240]

714. The European Medicines Agency, the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "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

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[238] *Id.* at 7.

[239] *Id.* at 10 n.43.

[240] 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. 13, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

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."[241]

K. Defendants' Conduct Damaged Plaintiffs and the Class Members

715. As a direct and proximate result of Defendants' breaches of express and implied warranties; failure to comply with CGMPs; failure to adequately inspect/test the drugs during the manufacturing process; failure to implement procedures to reduce or eliminate NDMA levels in Ranitidine-Containing Products; defective design and formulation of their products; misrepresentation, concealment, omission, and failure to disclose material facts concerning the safety and efficacy of their products; breaches of their duty to provide appropriate and accurate instructions regarding the proper storage and handling of Ranitidine-Containing Products; and breaches of their duty of reasonable care and failure to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, Plaintiffs and the Class members suffered damages through (1) their purchase of Ranitidine-Containing Products that are unsafe for human consumption; and (2) their ingestion of Ranitidine-Containing Products, which have significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

716. Plaintiffs and Class members were exposed to Defendants' uniform misrepresentations and omissions regarding the purported safety of their Ranitidine-Containing

[241] European Medicines Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/medicines/human/referrals/ranitidine-containing-medicinal-products.

Products, including the representations that such products were safe for frequent use, safe to treat chronic conditions, and safe to take with nitrite- and nitrate-rich foods.

717. As alleged herein, these misrepresentations were false, deceptive, and misleading when made because Defendants' Ranitidine-Containing Products contained an inherently unstable ranitidine molecule that breaks down into unreasonably dangerous levels of NDMA when ingested, especially with nitrite- and nitrate-rich foods, and ultimately increases a user's risk of developing cancer.

718. As alleged herein, Defendants knew or should have known that NDMA is a clearly carcinogenic chemical and that the ranitidine molecule in their Ranitidine-Containing Products is unstable and degrades into NDMA under normal conditions that are exacerbated when combined with gastric fluid or nitrite- and nitrate-rich foods, or when the drug is exposed to normal levels of heat during the manufacture, transportation, and storage processes.

719. Despite having actual or constructive knowledge of the foregoing material facts, Defendants concealed and/or failed to disclose, for example, that (1) their Ranitidine-Containing Products contained an unstable ranitidine molecule that breaks down into a carcinogen under normal conditions; (2) this breakdown is exacerbated when the drug is ingested, mixed with nitrite- and nitrate-rich foods, or when exposed to heat; (3) Defendants failed to comply with cGMPs; (4) Defendants failed to conduct stability testing of their Ranitidine-Containing Products to assess the stability characteristics and ensure bioequivalence; (5) Defendants took no precautions, or took inadequate precautions, to protect ranitidine from exposure to heat during the manufacture, transportation, and storage processes; (6) as a result of the foregoing, Defendants' Ranitidine-Containing Products were misbranded and adulterated and, thus, could not lawfully be sold in the U.S.; and (7) consumption of Ranitidine-Containing Products increases the risk of cancer.

720. These facts are material as the relate to the safety of a drug intended for human consumption and the propensity of the drug to cause cancer when used as directed. These facts would be considered important and material by any reasonable consumer. No reasonable consumer would have purchased or ingested Defendants' Ranitidine-Containing Products had Defendants disclosed these material facts.

721. At the time they purchased Defendants' Ranitidine-Containing Products, Plaintiffs and the Class members did not know, and could not have discovered through reasonable diligence, the material facts regarding the safety and risks of Ranitidine-Containing Products that Defendants concealed and/or failed to disclose. Plaintiffs and Class members reasonably and justifiably relied on Defendants' misrepresentations, omissions, concealments, and/or failure to disclose materials facts about the Ranitidine-Containing Products. Had Defendants disclosed the true facts regarding the purported safety of Ranitidine-Containing Products, Plaintiffs and the Class members would not have purchased nor ingested Defendants' Ranitidine-Containing Products.

722. Thus, as a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and Class members have suffered damages and out-of-pocket losses and did not receive the benefit of their bargain in that they paid to purchase misbranded, adulterated, defective, deceptively marketed, and unreasonably dangerous drugs they otherwise would not have purchased.

723. In addition, as a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the Class members who ingested Defendants' Ranitidine-Containing Products have suffered physical damages in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers. The nature of the latent injuries from which Plaintiffs and Class members suffer and the inadequacy of monetary damages as a means to compensate Plaintiffs and Class members for the

risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products necessitates the implementation of a Court-supervised, Defendant-funded medical monitoring fund to monitor and treat Plaintiffs and Class members for various cancers they risk developing as a result of Defendants' conduct.

724. Thus, Plaintiffs and Class members have suffered a concrete and particularized harm that is actual and/or imminent, and that is fairly traceable to Defendants' unlawful conduct. A favorable decision by this Court is likely to redress the injuries suffered by Plaintiffs and the Class members.

IV. EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

A. Discovery-Rule Tolling

725. Within the period of any applicable statutes of limitation, Plaintiffs and members of the proposed Classes (defined below) could not have discovered through the exercise of reasonable diligence that Defendants were not disclosing the high levels of the carcinogen, NDMA, in Ranitidine-Containing Products, including Zantac.

726. Plaintiffs and the other Class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants did not disclose the high levels of NDMA in Ranitidine-Containing Products, including Zantac. The information linking ranitidine to NDMA was contained exclusively in articles published in scientific journals and intended for the scientific audience. Plaintiffs and Class members did not have access to these scientific articles because they were behind a paywall. And even if the articles had been more widely available, the significance of the information in these highly technical articles would not have been apparent to Plaintiffs or Class members.

727. Plaintiffs and Class members could not have reasonably discovered the true extent of Defendants' deception with regard to the safety of Ranitidine-Containing Products until Valisure filed its citizen petition disclosing the extremely high levels of NDMA in Ranitidine-Containing Products, including Zantac.

728. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent-Concealment Tolling

729. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment of the fact that the ranitidine in Ranitidine-Containing Products, including Zantac, produces high levels of the carcinogen NDMA when ingested.

730. Instead of disclosing the link between ranitidine and the carcinogen, NDMA, Defendants continued to manufacture and sell Ranitidine-Containing Products without disclosing this information on the drug's label or anywhere else.

C. Estoppel

731. Defendants were under a continuous duty to disclose to Plaintiffs and the other Class members the risk of NDMA exposure associated with Ranitidine-Containing Products, including Zantac.

732. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Ranitidine-Containing Products, including Zantac, and never updated the drug's label to disclose this risk.

733. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

V. CLASS ALLEGATIONS

A. Nationwide Classes

734. All Plaintiffs bring this action in their individual capacity and on behalf of the following Nationwide Classes pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **RICO Class:** All residents of the United States or its territories who purchased for personal, family, or household use any of Brand-Name Manufacturer Defendants' Ranitidine-Containing Products in the United States or its territories.
>
> **Nationwide Class:** All residents of the United States or its territories who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories.

735. Excluded from the Nationwide 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.

736. Plaintiffs reserve the right to modify or amend the definitions of the Nationwide Classes, including to add one or more subclasses, after having the opportunity to conduct discovery.

B. State Classes

737. As an alternative and/or in addition to Nationwide Class, Plaintiffs bring this action in their individual capacities and on behalf of the following State Classes for all fifty states of the United States of America, the District of Columbia, and Puerto Rico pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **[State] Class:** All residents of [State or Territory] who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories.

738. 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.

739. Plaintiffs reserve the right to modify or amend the definitions of State Classes, including to add one or more subclasses, after having the opportunity to conduct discovery.

740. The Nationwide Classes and the State Classes are collectively referred to as "Class," except where otherwise specified.

C. Federal Rule of Civil Procedure 23 Requirements

741. Each of the proposed Classes meets the requirements of Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3) and/or 23(c)(4).

742. ***Numerosity.*** The members of each 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 Class includes thousands if not millions of members who are geographically dispersed throughout the country and/or throughout each respective state.

743. ***Typicality.*** Plaintiffs' claims are typical of the claims of putative Class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the claims of the other Class members. Each Plaintiff, like each Class member, either took or paid money to purchase 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 Class member, either suffered out-of-pocket loss and/or face an increased risk of developing cancer. Plaintiffs, like each Class member, were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the Class members.

744. ***Adequacy.*** Plaintiffs will fairly and adequately protect the interests of the Class members. Plaintiffs' interests and the interests of all other members of each respective Class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the Class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

745. ***Commonality and Predominance.*** There are numerous questions of law and fact common to the Classes, and these common questions predominate over any issues affecting only individual Class members. Questions common to the Classes include, but are not limited to, the following:

(a) whether Ranitidine-Containing Products, including Zantac, contains or exposed Class members to unsafe levels of NDMA;

(b) whether consumption of Ranitidine-Containing Products, including Zantac, increases the risk of developing cancer;

(c) whether Defendants knew or should have known that Ranitidine-Containing Products, including Zantac, contains unacceptable levels of NDMA;

(d) whether Defendants knew or should have known that consumption of Ranitidine-Containing Products, including Zantac, increases the risk of developing cancer;

(e) whether Defendants acted to conceal the fact that Ranitidine-Containing Products, including Zantac, exposes users to unsafe quantities of NDMA;

(f) whether Defendants acted to conceal the fact that consumption of Ranitidine-Containing Products, including Zantac, increases the risk of developing cancer;

(g) whether Defendants' marketing, advertising, or promotion of ranitidine, including Zantac, misrepresented the safety of ranitidine and/or Zantac, or failed to disclose that Ranitidine-Containing Products, including Zantac, produces high levels of the carcinogen NDMA;

(h) whether Defendants' marketing, advertising, or promotion of Ranitidine-Containing Products, including Zantac, misrepresented the safety of Ranitidine-Containing Products, or failed to disclose that consumption of Ranitidine-Containing Products increases the risk of developing cancer;

(i) whether Defendants' failure to disclose that Ranitidine-Containing Products, including Zantac, produce high levels of the carcinogen NDMA was unfair, deceptive, fraudulent, or unconscionable;

(j) whether Defendants' failure to disclose that consumption of Ranitidine-Containing Products, including Zantac increase the risk of developing cancer was unfair, deceptive, fraudulent, or unconscionable;

(k) whether Defendants' conduct was knowing or willful;

(l) whether Defendants' conduct violated state consumer-protection statutes;

(m) whether Defendants were negligent in selling Ranitidine-Containing Products, including Zantac;

(n) whether Defendants are strictly liable for designing or manufacturing Ranitidine-Containing Products, including Zantac, or for failing to warn of the risks associated with use of the drug;

(o) whether Plaintiffs and the Class members are entitled to medical monitoring because of their exposure to Ranitidine-Containing Products, including Zantac;

(p) whether Defendants breached express warranties;

(q) whether Defendants breached implied warranties;

(r) whether Defendants have been unjustly enriched;

(s) whether Defendants' conduct violated the MMWA, 15 U.S.C. §2301, *et seq.*;

(t) whether Defendants conducted an enterprise in violation of RICO, 18 U.S.C. §1961, *et seq.*;

(u) whether Plaintiffs and the Class members are entitled to recover damages and the appropriate measure of those damages;

(v) the appropriate measure of disgorgement; and

(w) the type and format of injunctive relief that is appropriate.

746. ***Superiority.*** A class action is superior to any 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 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 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 far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

747. ***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 Class as a whole, such that final injunctive relief is appropriate with respect to the Class as a whole. Such injunctive relief includes, but is not limited to, the implementation and funding of a medical monitoring program for Plaintiffs and Class members that is sufficient to monitor their health and to ensure the early detection of diseases, specifically cancers caused by ingesting ranitidine.

748. Plaintiffs reserve the right to seek certification under Rule 23(c)(4) of common questions related to Defendants' knowledge, conduct, products, and duties.

CAUSES OF ACTION

VI. CAUSE OF ACTION BROUGHT ON BEHALF OF THE RICO CLASS

COUNT 1
Violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1962(c)-(d)
(Against RICO Defendants)

749. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

750. Plaintiffs bring this Count on behalf of the RICO Class (for the purpose of this section, the "Class") against Sanofi, BI, Pfizer, and GSK (for purpose of this Count, these Defendants are collectively referred to as "RICO Defendants").

751. Plaintiffs and other Class Members are "persons" within the meaning of 18 U.S.C. §1961(3), and each is a "person injured in his [or her] business or property" by reason of RICO Defendants' violation of RICO within the meaning of 18 U.S.C. §1964(c).

752. At all relevant times, each RICO Defendant has been a "person" within the meaning of 18 U.S.C. §1961(3) because each was capable of holding "a legal or beneficial interest in property."

753. RICO Defendants conduct their business – both legitimate and illegitimate – by and through various affiliates and subsidiaries, each of which is a separate legal entityBI operates by and through Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation, among others. Sanofi operates by and through Sanofi S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., and Chattem, Inc., among others. GSK operates by and through GlaxoSmithKline plc, GlaxoSmithKline LLC, and GlaxoSmithKline (America) Inc., among others. Pfizer also operated by and through various affiliates and subsidiaries at all relevant times. Defendants have

also formed joint ventures and other agreements between and among each other at various points in time during the scheme as detailed herein.

A. Zantac RICO Enterprise

754. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

755. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. §1962(d).

756. Zantac, the trade name for ranitidine, was for years the world's top selling drug and the first to top $1 billion in annual sales. The unprecedented success of Zantac was not an accident. It was the direct result of aggressive marketing by RICO Defendants and others that pushed Zantac as safe and effective for consumers. In their quest to reach ever new heights of sales and profits, RICO Defendants recklessly continued to push Zantac as safe and effective even after they became aware of the NDMA risks associated with ranitidine consumption.

757. Instead of pulling Zantac from the shelves or warning the public and regulators about its safety risks, RICO Defendants hid the truth. To do so, each Defendant was employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (defined below and referred to collectively as the "Zantac RICO Enterprise"), whose purpose was to conceal or downplay the safety risks of Zantac. The motivation was simple: to increase Defendants' revenues and profits and minimize their losses from the manufacture and sale of Zantac. As a direct and proximate result of their fraudulent scheme and common course of conduct, RICO Defendants were able to extract billions of dollars from Plaintiffs and the Class. It

was not until recently that Zantac remained on retail and pharmacy shelves in the United States. RICO Defendants' decades-long scheme violated Sections 1962(c) and (d) of RICO statute.

758. At all relevant times, RICO Defendants, along with other individuals and entities, including unknown third parties involved in the formulation, manufacture, and sale of Zantac operated an association-in-fact enterprise, which was formed for the purpose of selling Zantac throughout the U.S. and through which enterprise(s) they conducted a pattern of racketeering activity under 18 U.S.C. §1961(4). The enterprise is referred to herein as the "Zantac RICO Enterprise."

759. At all relevant times, the Zantac RICO Enterprise constituted a single "enterprise" or multiple enterprises within the meaning of 18 U.S.C. §1961(4), as legal entities, as well as individuals and legal entities associated-in-fact for the common purpose of engaging in RICO Defendants' unlawful profit-making scheme.

760. The association-in-fact Zantac RICO Enterprise consisted of at least the following entities and individuals, and likely others:

(a) Sanofi S.A. is a French multinational pharmaceutical company headquartered in Paris and listed on the NASDAQ. As of June 8, 2020, it had a market capitalization of $63.7 billion. The other Sanofi Defendants are not publicly traded and thus have no SEC reporting obligations, but they do have reporting obligations, protections and responsibilities unique to their respective home states.

(b) BI is a German multinational company and one of the world's largest pharmaceutical companies and the largest private one. BI operates with 146 affiliates and is owned by the Boehringer, Liebrecht, and von Baumbach families.

(c) GlaxoSmithKline plc is a British multinational pharmaceutical company headquartered in the United Kingdom and listed on the New York Stock Exchange. As of June 8, 2020, it had a market capitalization of $105 billion. The other GSK Defendants are not publicly traded and thus have no SEC reporting obligations, but do have reporting obligations, protections and responsibilities unique to their respective home states.

(d) Pfizer is an American multinational pharmaceutical company headquartered in New York City and listed on the New York Stock Exchange. As of June 8, 2020, it had a market capitalization of $203 billion. Other Pfizer entities or divisions, such as Warner-Lambert Consumer Healthcare, are not publicly traded and thus have no SEC reporting obligations but do have reporting obligations, protections and responsibilities unique to their respective home states.

761. At all relevant times, the Zantac RICO Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Sanofi Defendants, the BI Defendants, the GSK Defendants, and Pfizer, and/or other entities and individuals associated for the common purpose of formulating, manufacturing, distributing, testing, and selling Zantac to Plaintiffs and the Nationwide Class by concealing safety risks and deriving profits and revenues therefrom.

762. Each member of the Zantac RICO Enterprise shared in the bounty generated by the enterprise, *i.e.*, by sharing the benefit derived from increased sales revenue generated by the scheme to defraud Class members nationwide. If any member of the Zantac RICO Enterprise had publicly revealed the safety risks, all would lose their revenues and profits from Zantac. At various points in time, RICO Defendants entered into joint ventures and/or other agreements concerning the rights to Zantac including for, example, the partnership between GSK and Warner Lambert resulting in Warner-Lambert Consumer Healthcare; Pfizer's acquisition of Warner Lambert; BI's acquisition of the rights to OTC Zantac; and Sanofi's acquisition of the rights to OTC Zantac.

763. The Zantac RICO Enterprise functioned by selling pharmaceutical products. Many of the products were legitimate, including products that are not known to form NDMA when consumed. However, RICO Defendants and their co-conspirators, through their illegal enterprise, engaged in a pattern of racketeering activity, which involves a fraudulent scheme to increase

revenues and minimize losses for Defendants and the other entities and individuals associated-in-fact with the enterprise's activities through their fraudulent scheme.

764. The Zantac RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce, because it involved commercial activities across both state and national boundaries, such as the marketing, promotion, advertisement, distribution, and sale of Zantac throughout the country and beyond, and the receipt of monies from the sale of the same.

765. Within the Zantac RICO Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis. The enterprise used this common communication network for the purpose of formulating, manufacturing, marketing, distributing, and selling Zantac nationwide.

766. Each participant in the Zantac RICO Enterprise had a systematic linkage to others through corporate ties, contractual relationships, financial ties, and continuing coordination of activities. Through the Zantac RICO Enterprise, RICO Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their profits and revenues, as well as minimizing their losses.

767. RICO Defendants participated in the operation and management of the Zantac RICO Enterprise by directing its affairs, as described herein. While RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

768. Each RICO Defendant exerted substantial control over the Zantac RICO Enterprise, and participated in, operated and/or directed the enterprise, by:

(a) concealing or downplaying safety risks from the public and regulators;

(b) misleading the public and regulators as to the nature and safe use of Zantac;

(c) formulating, manufacturing, distributing, promoting, and/or selling Zantac;

(d) misrepresenting or omitting safety risks (or causing such misrepresentations and omissions to be made) in promotional materials or advertisements;

(e) concealing or downplaying safety risks in scientific studies;

(f) misrepresenting or omitting (or causing such misrepresentations and omissions to be made) safety risks on FDA applications and other communications with regulators;

(g) introducing Zantac into the stream of U.S. commerce with concealed safety risks;

(h) entering into joint ventures or agreements concerning the rights to Zantac;

(i) persisting in the manufacturing, distribution, and sale of Zantac even after questions were raised about safety risks;

(j) collecting revenues and profits in connection with the sale of Zantac; and/or

(k) ensuring that the other RICO Defendants and unnamed co-conspirators complied with the scheme or common course of conduct.

769. Without RICO Defendants' willing participation, the Zantac RICO Enterprise's years-long scheme and common course of conduct would have been unsuccessful.

770. RICO Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiffs cannot fully know at present, because such information lies in Defendants' and others' hands. Similarly, because the Defendants often refer to themselves as a group (*i.e.*, "Sanofi," "Boehringer Ingelheim," "GSK," etc.), Plaintiffs cannot fully know the full extent of each individual corporate entity's involvement in the wrongdoing prior to having access to discovery.

B. Mail and Wire Fraud

771. To carry out, or attempt to carry out the scheme to defraud, RICO Defendants, each of whom is a person associated-in-fact with the Zantac RICO Enterprise, did knowingly conduct

or participate, directly or indirectly, in the conduct of the affairs of the Zantac RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

772. Specifically, as alleged herein, RICO Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§1341 and 1343). The multiple acts of racketeering activity that RICO Defendants committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by RICO Defendants' regular use of the facilities, services, distribution channels, and employees of RICO Defendants in the Zantac RICO Enterprise. RICO Defendants participated in the scheme to defraud by using e-mail, mail, telephone, facsimile, TV, radio, and the internet to transmit mailings and wires in interstate or foreign commerce.

773. RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions.

774. In devising and executing the illegal scheme, RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and the Nationwide Class or to obtain money from them by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

775. RICO Defendants' predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

(a) Mail Fraud: RICO Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing their unlawful scheme to manufacture, market, and sell Zantac by concealing or downplaying its safety risks.

(b) Wire Fraud: RICO Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money by concealing or downplaying the safety risks of Zantac.

776. RICO Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery, or shipment of the following, which were foreseeably caused to be sent as a result of RICO Defendants' illegal scheme:

(a) Zantac tablets, capsules, injections, syrup, and/or granules;

(b) false or misleading websites;

(c) false or misleading industry publications and/or studies;

(d) false or misleading sales and marketing materials, including websites, ads, and brochures concealing the true nature of Zantac, such as the multi-media "Captain Zantac" campaign;

(e) false or misleading product packaging and labels;

(f) false or misleading FDA applications and other government communications;

(g) fraudulently obtained governmental approvals;

(h) false or misleading communications intended to lull the public and regulators from discovering the true nature of Zantac;

(i) documents and communications that facilitated the scheme, including but not limited to, invoices, shipping records, reports, and correspondence;

(j) millions of dollars in compensation to company executives;

(k) deposits of proceeds; and/or

(l) other documents and things.

777. RICO Defendants (or their agents), for the purpose of executing the illegal scheme, transmitted (or caused to be transmitted) in interstate commerce by means of wire communications, certain writings, signs, signals and sounds, including the items described above and the following examples:

778. RICO Defendants used the internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. Specifically, RICO Defendants omitted safety risks of Zantac on websites, YouTube, Facebook, Twitter, and other online advertising, all of which were intended to mislead the public and regulators.

From	**To**	**Date**	**Description**
Sanofi subsidiary, Chattem Inc., Chattenooga, Tennessee	Twitter, San Francisco, California	September 3, 2019	Twitter feed: "The Captain likes his wings 4-alarm spicy."
Sanofi subsidiary, Chattem Inc., Chattenooga, Tennessee	YouTube, San Mateo, California	July 3, 2019	Online Video Ad: "S. O. Neal: No Mess Fast Relief Heart Burn Night"
Sanofi subsidiary, Chattem Inc., Chattenooga, Tennessee	YouTube, San Mateo, California	March 14, 2019	Zantac TV Commercial, "Family Taco Night"
GSK, United Kingdom	US Healthcare Professionals via GSK Direct website	Throughout 2018	Zantac 150 Tablets 500's product description for US Healthcare professionals online
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	YouTube, San Mateo, California	March 7, 2017	Online Video Ad: "Releases Cooling Sensation in Mouth and Throat"
Boehringer Ingelheim Pharmaceuticals,	Sanofi US, Bridgewater, New Jersey	February 24, 2017	Transfer of domain ownership of "RethinkPPIs.com" website claiming that non-prescription

From	To	Date	Description
Inc., Ridgefield, Connecticut			Zantac has "no long-term safety concerns."
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	PR Newswire, New York, New York	September 9, 2013	Press release re: launch of "Captain Zantac™" 360-degree brand equity campaign with national TV ads, print, online, and retail advertising
Pfizer, New York, New York	Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	October 13, 2006	Agreements and related correspondence re: BI acquisition of OTC rights to Zantac from Pfizer

779. RICO Defendants (or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of Zantac drugs, and related documents by mail or a private carrier affecting interstate commerce, including the items described above and the following examples:

From	To	Date	Description
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	ESPN Magazine	March 2, 2015	Print Ad: "CAPTAIN Zantac IN HEARTBURN RESCUE: Stop! That heartburn pill can take 24 hours to work! Zantac is different! Zantac rushes relief in as little as 30 minutes. Zantac. No pill relieves heartburn faster!"
GlaxoSmithKline, Research Triangle Park, North Carolina	U.S. Food & Drug Administration, Silver Spring, Maryland	September 4, 2009	Zantac FDA Label
Pfizer Consumer Healthcare, Richmond, Virginia	Madison Wisconsin State Journal	November 2, 2003	Print Ad: "Zantac 75 relieves heartburn fast, right when you need it. Prilosec OTC doesn't."
U.S. Patent & Trademark Office, Alexandria, Virginia	Warner-Lambert Company	February 2, 1996	Trademark statement of use processing complete

780. RICO Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various other affiliates, regional offices, divisions, dealerships and other third-party entities in furtherance of the scheme.

781. The mail and wire transmissions described herein were made in furtherance of RICO Defendants' scheme and common course of conduct to sell Zantac, which Defendants knew or recklessly disregarded as forming NDMA in the body.

782. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

783. RICO Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d), RICO Defendants conspired to violate 18 U.S.C. §1962(c), as described herein. Various other persons, firms and corporations, including third-party entities and individuals not currently named as defendants, have participated as co-conspirators with RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for RICO Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

784. RICO Defendants had knowledge of the fraud and aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

785. To achieve their common goals, RICO Defendants hid or downplayed the dangers of Zantac and obfuscated its true nature even after regulators and others raised concerns. RICO Defendants suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the safety risks of Zantac.

786. RICO Defendants and each member of the conspiracy, with knowledge and intent, have agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud in formulating, manufacturing, distributing, marketing, and/or selling Zantac.

787. Indeed, for the conspiracy to succeed each RICO Defendant and their co-conspirators had to agree to implement and use the similar devices and fraudulent tactics—specifically concealing or downplaying the safety risks of Zantac forming NDMA in the body.

788. RICO Defendants knew and intended that the public and regulators would rely on their material omissions. RICO Defendants knew and intended that Plaintiffs and the Nationwide Class would incur costs as a result. In fact, Plaintiffs, along with the consuming public and others across the country, relied upon the concealment of material facts caused by them. Plaintiffs' reliance is made obvious by the fact that they bought drugs that were not safe for use and never should have been introduced into the U.S. stream of commerce as made plain by the fact that they have been pulled from the shelves now.

789. Unbeknownst to Plaintiffs and the Nationwide Class, RICO Defendants engaged in a pattern of related and continuous predicate acts for many years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiffs and Class members based on the concealment of the truth, while providing Zantac drugs that were worth significantly less than the purchase price paid. The

predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

790. The predicate acts all had the purpose of generating significant revenue and profits for RICO Defendants (and minimizing their losses) at the expense of Plaintiffs and Class members. The predicate acts were committed or caused to be committed by RICO Defendants through their participation in the Zantac RICO Enterprise and in furtherance of the scheme, and were interrelated in that they involved obtaining Plaintiffs' and Class members' funds and avoiding the expenses and loss of revenues associated with recalling the drugs.

791. During the formulation, manufacture, marketing, and sale of Zantac, RICO Defendants came across and/or shared information about the risk that ranitidine would form a cancer-causing chemical in the body. Nevertheless, RICO Defendants shared and/or disseminated information that misrepresented Zantac as safe while concealing its risks.

792. By reason of, and as a result of the conduct of RICO Defendants, and in particular, their pattern of racketeering activity, Plaintiffs and Class members have been injured in their business and/or property in multiple ways, including, but not limited to,:

(a) the purchase price of Zantac;

(b) overpayment for Zantac; and/or

(c) other out-of-pocket expenses.

793. RICO Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiffs and Class members. Plaintiffs and Class members are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c).

VII. CAUSES OF ACTION BROUGHT ON BEHALF OF THE NATIONWIDE CLASS

COUNT 2
Unjust Enrichment
(Against All Defendants)

794. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

795. This cause of action is brought on behalf of the Nationwide Class (for purposes of this section, "Class") against all Defendants under the common law of unjust enrichment. In the alternative, Plaintiffs bring this cause of action on behalf of themselves under the laws of the state in which each Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of a Class comprised of members from each Plaintiff's respective state.

796. Plaintiffs and Class members conferred a benefit on Defendants in the form of payment of monies to purchase worthless Ranitidine-Containing Products, or were otherwise in privity with Defendants through said transaction.

797. In exchange for their payment of the purchase price of Defendants' Ranitidine-Containing Products, Plaintiffs and Class members reasonably expected they would receive safe and effective medications. However, because the Ranitidine-Containing Products contained dangerously high levels of NDMA, the medications were unfit for human consumption and therefore unfit for their intended purpose.

798. As a result of the Defendants' misrepresentations and omissions, Plaintiffs and Class members were not aware of the true facts concerning the Ranitidine-Containing Products and did not benefit from the Defendants' misconduct.

799. The Defendants readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from their unjust conduct – at Plaintiffs' and the Class

members' expense – by selling worthless Ranitidine-Containing Products that were unfit for their intended use and unsafe for human consumption.

800. It is inequitable and unconscionable for the Defendants to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and members of the Class, who would not have purchased the medications at all, but for the Defendants' misrepresentations and omissions. Additionally, the Defendants' distribution and sale of Ranitidine-Containing Products in the United States was illegal because they were adulterated, misbranded, and unfit for human consumption.

801. Equity cannot in good conscience permit the Defendants to retain the benefits derived from Plaintiffs and Class members through their unjust and unlawful acts, and therefore restitution or disgorgement of the amount of their unjust enrichment is required.

802. Plaintiffs and members of the Class do not have an adequate remedy at law.

COUNT 3
Violations of the Magnuson-Moss Warranty Act, 15 U.S.C. §2301, *et seq.*
(Against All Defendants)

803. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

804. This cause of action is brought on behalf of the Nationwide Class (for purposes of this section, "Class") against all Defendants.

805. Plaintiffs and members of the Class are "consumer[s]" within the meaning of 15 U.S.C. §2301(3).

806. Each Defendant is a "supplier" and "warrantor" within the meaning of 15 U.S.C. §2301(4) and (5), respectively.

807. The Ranitidine-Containing Products purchased by Plaintiffs and members of the Class are "consumer product[s]" within the meaning of 15 U.S.C §2301(1).

808. 15 U.S.C. §2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a supplier or warrantor to comply with a written or implied warranty.

809. The amount in controversy of Plaintiffs' individual claims meets or exceeds $25.00 in value. In addition, the amount in controversy meets or exceeds $50,000 in value (exclusive of interest and costs) on the basis of all claims to be determined in this lawsuit.

810. At all relevant times, the Defendants expressly represented and warranted to the purchasers of their products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Ranitidine-Containing Products were safe for human consumption and fit to be used for their intended purpose. The Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Ranitidine-Containing Products would conform to the Defendants' representations.

811. Defendants represented to Plaintiffs and members of the Class via media, advertising, marketing, websites, social media, packaging, labeling, and promotions that:

(a) Ranitidine-Containing Products were both safe and effective for the lifetime of the product, when in fact, they contain unsafe levels of NDMA – far exceeding the 96 ng limit – and which increase as the product ages;

(b) consumption of Ranitidine-Containing Products would not result in excessive amounts of NDMA accumulating in their bodies;

(c) the levels of NDMA in Ranitidine-Containing Products have no practical clinical significance; and

(d) Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew or should have known, they were unsafe for their intended purpose.

812. The representations about Ranitidine-Containing Products, as alleged herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

813. Defendants breached these express warranties because, among other things, Ranitidine-Containing Products were defective, dangerous, and were not merchantable or safe for their intended use.

814. Under state law, a warranty that goods shall be merchantable is implied in every contract for the sale of goods by a merchant that deals in such goods. Before Plaintiffs' and Class members' purchase and/or use of Ranitidine-Containing Products, the Defendants impliedly warranted to their consumers, including Plaintiffs and members of the Class, that Ranitidine-Containing Products were of merchantable quality and safe and fit for their intended use; specifically, as consumer medication.

815. Plaintiffs and members of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

816. Plaintiffs and each member of the Class have had sufficient direct dealings with Defendants or their agents (including distributors and dealers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

817. Defendants breached their implied warranty to Plaintiffs and members of the Class in that Ranitidine-Containing Products were not of merchantable quality, safe, nor fit for their

intended use. Ranitidine-Containing Products have dangerous propensities when used as intended and can cause serious injuries.

818. As a direct and proximate result of Defendants' breach of the written and implied warranties, Plaintiffs and members of the Class have suffered damages. Plaintiffs and Class members would not have purchased the drug, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

819. No Defendant has acted upon the opportunity to cure its failure to uphold its express and implied warranties concerning the Ranitidine-Containing Products.

820. The warranty laws of each state, which are hereby incorporated into this Count, are set forth below.

821. As a result of Defendants' breaches of express and implied warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 4
Common Law Fraud
(Against Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Repackager Defendants)

822. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

823. This cause of action is brought on behalf of the Nationwide Class (for purposes of this section, "Class") against Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Repackager Defendants (for purposes of this section, "Defendants") under the common law of fraud. In the alternative, Plaintiffs bring causes of action on behalf of themselves under the laws of the state in which each Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of each State Class.

824. At all relevant times, Defendants knew that the Ranitidine-Containing Products contained unsafe levels of NDMA.

825. Defendants falsely represented – affirmatively or by omission – to Plaintiffs and the Class via media, advertising, marketing, websites, social media, packaging, labeling, and promotions that:

(a) Ranitidine-Containing Products were both safe and effective for the lifetime of the product, when in fact, they contain unsafe levels of NDMA – far exceeding the 96 ng limit – and which increase as the product ages;

(b) consumption of Ranitidine-Containing Products would not result in excessive amounts of NDMA accumulating in their bodies;

(c) the levels of NDMA in Ranitidine-Containing Products have no practical clinical significance; and

(d) Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew, or should have known, they were unsafe for their intended purpose.

826. Defendants' representations were false at the time they were made, Defendants had knowledge of their falsity or acted with reckless disregard as to their truth, and intended for Plaintiffs and the Class to rely on the false representations so that they would purchase and consume the Ranitidine-Containing Products.

827. These misrepresented, omitted, and undisclosed facts were material because they would be reasonably and justifiably relied on by a reasonable person, like Plaintiffs and the Class members, in deciding whether to purchase or use Ranitidine-Containing Products and because they render the Ranitidine-Containing Products worthless.

828. Defendants knowingly and intentionally omitted, concealed, and/or failed to disclose to Plaintiffs, the Class, the healthcare industry, and the public, these material facts regarding the Ranitidine-Containing Products' dangers.

829. Defendants had a duty to disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe for human consumption because:

(a) Defendants had exclusive and/or far superior knowledge and access to the facts regarding the defects associated with the Ranitidine-Containing Products than Plaintiffs and members of the Class, and Defendants knew the facts regarding defects associated with the Ranitidine-Containing Products were not known to, or reasonably discoverable by, Plaintiffs and members of the Class;

(b) the defect in the Ranitidine-Containing Products was a valuable fact that was not disclosed to Plaintiffs and members of the Class because if Plaintiffs and members of the Class had been apprised of the true nature of the medications, they would not have purchased or used the medications;

(c) Plaintiffs and members of the Class had no opportunity to ascertain the facts regarding the true nature of the medications and could not have done so through exercise of reasonable diligence;

(d) Defendants intentionally concealed the foregoing from Plaintiffs and members of the Class; and

(e) Defendants knew that the defects associated with the Ranitidine-Containing Products were facts basic to the transaction that Plaintiffs and Class members would reasonably expect to be disclosed, and knew that Plaintiffs or the Class would purchase the Ranitidine-Containing Products under the mistaken belief that they were safe for human consumption.

830. Given Defendants' exclusive knowledge of the defect in the Ranitidine-Containing Products, equity and good conscience mandate that Defendants should have disclosed the defect to Plaintiffs and the Class.

831. As set forth at length above, Defendants actively concealed a material fact with an intent to deceive or mislead. Defendants additionally had a duty to disclose because the nature of the facts not disclosed by Defendants was material to Plaintiffs' and the Class's decision to purchase the medications. If Plaintiffs and the Class had known the true nature of the medications, they would not have purchased them.

832. Plaintiffs and the Class reasonably and justifiably relied on Defendants' misrepresented, omitted, concealed, and undisclosed material facts about the Ranitidine-Containing Products, including facts related to their safety and efficacy and the severity, duration, and extent of risk associated with their use.

833. Defendants misrepresented, omitted, concealed, and/or failed to disclose these material facts to protect their profits and to avoid recalls that would hurt their brands' images and cost the Defendants money.

834. Defendants' fraudulent conduct directly and proximately caused Plaintiffs and the Class to: (a) be subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustain a significantly increased risk of developing various types of serious and potentially deadly cancers.

835. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

836. Further, as a direct and proximate result of Defendants' concealment, omission, and/or failure to disclose material facts, Plaintiffs and the Class suffered damages through their purchase of Ranitidine-Containing Products that are unsafe for human consumption. Had Defendants not omitted, concealed, and failed to disclose material facts as alleged herein, Plaintiffs would not have purchased the drug.

837. As a result of Defendants' fraudulent conduct, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased and, thus, did not receive the benefit of the bargain and suffered out-of-pocket loss.

VIII. CAUSES OF ACTION BROUGHT ON BEHALF OF STATE CLASSES

COUNT 5
Negligence
(Against All Defendants)

838. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

839. This cause of action is brought on behalf of the Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming Classes (collectively for the purposes of this section, the "Class") against all Defendants.

840. The Connecticut Class brings this product liability action under the Connecticut Products Liability Act, Conn. Gen. Stat. §52-572m, *et seq*.

841. The Michigan Class brings this product liability action pursuant to Michigan Compiled Laws §§600.2945-600.2949.

842. The New Jersey Class brings this action only as it relates to claims predicated on Defendants' negligent conduct and the harm that conduct caused to Plaintiffs and New Jersey Class members.

843. The Puerto Rico Class brings this action pursuant to Article 1802 of the Puerto Rico Civil Code, P.R. Laws tit. 31, §5141.

844. The Ohio Class brings this action only as it relates to the economic harm Plaintiffs and Ohio State Class members suffered due to Defendants' negligence.

845. The Oregon Class brings this product liability action pursuant to the Oregon Products Liability Act, Or. Rev. Stat. Ann. §30.900, *et seq*., except as to the allegations related to Defendants' post-sale conduct and the resulting harm therefrom, which the Oregon Class members bring under state common-law.

846. Defendants, directly or indirectly, caused Ranitidine-Containing Products to be sold, distributed, marketed, promoted, and/or used by Plaintiffs and Class members.

847. At all relevant times, Defendants had a duty to exercise reasonable care and act as a similarly situated and reasonably prudent designer, manufacturer, packager, distributor, and/or seller would in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products so as to prevent harm to others, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to foreseeable users and consumers.

848. At all relevant times, Defendants had the duty to stay current on scientific developments relevant to Ranitidine-Containing Products, to possess the knowledge available to reasonable pharmaceutical manufacturers, distributors, and packagers in similar positions, and to apply that information in order to recognize and consider the foreseeable and unreasonable risks of harm that Ranitidine-Containing Products posed to users and consumers.

849. At all relevant times, Defendants' duty included exercising ordinary and due care to adequately test and inspect Ranitidine-Containing Products and the chemical compounds used therein so as to recognize and prevent any condition that rendered Ranitidine-Containing Products unsafe for their intended or foreseeable use.

850. Additionally, at all relevant times, Defendants had a duty to exercise reasonable care in providing both OTC users and consumers and prescription users' healthcare providers with: (a) specific directions for safe use of Ranitidine-Containing Products; (b) accurate, true, and correct information concerning the known or foreseeable risks of using Ranitidine-Containing Products as directed; and (c) appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products when used as intended – in particular, their ability to transform into carcinogenic compound, NDMA – through a means that could reasonably be expected to reach foreseeable users and consumers. Defendants had a duty to provide adequate warnings while Ranitidine-Containing Products remained on the market.

851. At all relevant times, Defendants had a further duty to avoid tendering into the marketplace a product which Defendants knew, or should have known, posed risks outweighing its benefits or which they knew, or should have known, was too dangerous to be used by anyone. Defendants' duty included exercising reasonable care to cease marketing and discontinue Ranitidine-Containing Products when Defendants knew, or had reason to know, that the product should not be used for any purpose considering its relative risks.

852. At all relevant times, Defendants knew – or in the exercise of ordinary and reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products' intended or foreseeable use. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products. Accordingly, Defendants knew, or reasonably should have known, that Ranitidine-Containing Products' carcinogenic properties made them so dangerous that they should not have been purchased or consumed by anyone.

853. Accordingly, at all relevant times, Defendants knew – or in the exercise of ordinary and reasonable care, should have known – that the NDMA in Ranitidine-Containing Products could foreseeably cause or be associated with Plaintiffs' and Class members' injuries and, thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and Class members.

854. Defendants had no reason to believe that foreseeable users and consumers of Ranitidine-Containing Products, including Plaintiffs and Class members, were aware of Ranitidine-Containing Products' potential to expose users to NDMA and/or of the magnitude of the non-obvious risks associated with the drugs' intended uses.

855. Defendants also knew – or in the exercise of ordinary and reasonable care, should have known – that healthcare providers would not be in a position to reduce the risks of harm to users and consumers who purchased Ranitidine-Containing Products without a prescription.

856. Accordingly, Defendants knew or reasonably should have known that Ranitidine-Containing Products' inherently dangerous properties – specifically, their propensity to transform into the carcinogenic NDMA poison when transported and consumed – far outweighed any benefit or utility derived from the product and any burden of remedying that danger.

857. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products in that Defendants: (a) manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; (b) knew, or had reason to know, of the defects inherent in their products; (c) knew, or had reason to know, that those defects created a significant risk of harm and unreasonably

dangerous side effects in the course of the drugs' intended use; (d) knew, or had reason to know, that consumers were unaware of the risks related to NDMA in Ranitidine-Containing Products; and (e) failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

858. Outside of the labeling context, Defendants were negligent in their promotion of Ranitidine-Containing Products by failing to prevent foreseeable harm and omitting material risk information as part of their promotion and marketing of Ranitidine-Containing Products through the media of internet, television, print advertisements, etc. Nothing prevented Defendants from presenting the truth concerning the risks associated with the use of Ranitidine-Containing Products in their promotional efforts. Indeed, Defendants had a duty to disclose the truth regarding those risks, outside of the context of labeling.

859. Despite their ability and ample means to investigate, study, and test their products and provide adequate warnings, Defendants failed to do so. Instead, Defendants wrongfully concealed information and made further false and misleading statements concerning the safety and use of Ranitidine-Containing Products.

860. Defendants' acts of negligence include, but are not limited to, the following:

(a) manufacturing, producing, formulating, creating, developing, designing, selling, and/or distributing Ranitidine-Containing Products without thorough and adequate pre- and post-market testing;

(b) manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Ranitidine-Containing Products while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Ranitidine-Containing Products and the carcinogenic potential of NDMA created in the human body as a result of ingesting Ranitidine-Containing Products, and, consequently, the risk of serious harm associated with human use of Ranitidine-Containing Products;

(c) failing to exercise reasonable and prudent care in the design, research, manufacture, and development of Ranitidine-Containing Products to avoid the risk of serious harm associated with the drugs' foreseeable use;

(d) introducing Ranitidine-Containing Products into the United States market despite knowing of the risks inherent to using ranitidine before the drugs' launch;

(e) failing to design and manufacture Ranitidine-Containing Products to ensure they were at least as safe and effective as other medications on the market intended to treat the same symptoms;

(f) failing to adopt a reasonable and available alternative design and continuing to design, manufacture, and introduce Ranitidine-Containing Products into the market despite knowing that the risks inherent to Ranitidine-Containing Products outweighed any utility or potential benefit derived from the product;

(g) failing to provide adequate instructions, guidelines, and safety precautions to persons that Defendants could reasonably foresee would use Ranitidine-Containing Products;

(h) failing to disclose to Plaintiffs and Class members, consumers, and the general public that use of Ranitidine-Containing Products presented severe risks of cancer;

(i) failing to warn Plaintiffs, Class members, consumers, and the general public that the drugs' risk of harm was unreasonable and that safer and effective alternatives were available;

(j) failing to warn of or disclose Ranitidine-Containing Products' unreasonable risk to prescribing physicians of foreseeable users;

(k) after obtaining additional information about the risks of Ranitidine-Containing Products post-sale, continually failing to warn users, consumers, and the medical profession of those risks;

(l) systematically suppressing, trivializing, and obscuring the scientific evidence of Ranitidine-Containing Products' dangerous characteristics and side effects while over exaggerating the weight of evidence regarding Ranitidine-Containing Products' safety;

(m) saturating the relevant markets available to Plaintiffs and Class members with Ranitidine-Containing Products despite knowing of the drugs' unreasonable danger compared to other treatment options;

(n) overstating Ranitidine-Containing Products' superiority compared with other heartburn treatments that do not contain ranitidine;

(o) representing before and after sale by and through statements in labels, publications, package inserts, and other written materials intended for the medical profession, consumers, and the general public that Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew, or should have known, the products were not safe for their intended purpose;

(p) declining to make or propose any changes to Ranitidine-Containing Products' labeling or other promotional materials that would alert consumers and the general public, including Plaintiffs and Class members, of the risks of Ranitidine-Containing Products;

(q) advertising, marketing, and recommending use of the Zantac products, while concealing and failing to disclose or warn of the dangers known by Defendants to be associated with or caused by the use of or exposure to Ranitidine-Containing Products;

(r) continuing to manufacture, advertise, promote, market, and sell of Ranitidine-Containing Products after obtaining additional, post-sale knowledge that the products were unreasonably unsafe and dangerous;

(s) failing to disclose the results of post-sale trials, tests, and studies of Ranitidine-Containing Products that evidenced the drugs' carcinogenic properties;

(t) knowingly preventing consumers from timely seeking appropriate and necessary medical treatment for the harmful health effects of NDMA by omitting potential serious and adverse side effects from their promotion, advertising, and marketing of Ranitidine-Containing Products;

(u) continuing to sell, promote, advertise, and market Ranitidine-Containing Products in the United States even after virtually every other nations' health agencies had banned sale of Ranitidine-Containing Products due to their unacceptable levels of NDMA; and

(v) continuing to sell, promote, advertise, market, and encourage the purchase and use of Ranitidine-Containing Products in the United States even after the FDA announced that it had found unacceptable levels of NDMA in the product.

861. Defendants were also negligent in that they labeled Ranitidine-Containing Products in a false and misleading manner that omitted any mention of the drugs' propensity to expose users

to NDMA and failed to suggest or recommend a manner of using Ranitidine-Containing Products so that they are not dangerous to users' and consumers' health when used as labeled and directed, thereby manufacturing, repackaging, offering for sale, delivering, and/or holding misbranded drugs in violation of 21 U.S.C. §§331, 352(a)(1), (j) and the following parallel state statutes:

- Alabama Code §§20-1-20(13) and 20-1-27(1);
- Alaska Statutes §§17.20.090(1), (10) and 17.20.290(a)(1);
- Arizona Statutes §§32-1965(1), (2) and 32-1967(1), (12);
- Arkansas Code §§20-56-211(1), (10) and 20-56-215(1);
- California Health and Safety Code §§111295, 11330, and 111440;
- Colorado Statutes §§25-5-403(1)(a), (b) and 25-5-415(1)(a), (j);
- Title 16, Delaware Code §§3302 and 3308(3);
- District of Columbia Code §48-702(2);
- Florida Statutes §§499.005(1) and 499.007(1), (10);
- Georgia Code §§26-3-3(1) and 26-3-8(a)(1), (10);
- Hawaii Revised Statutes §§328-6(1) and 328-15(1), (10);
- Idaho Code §§37-115(a) and 37-127(a), (j);
- Chapter 410, Illinois Statutes §§620/3.1 and 620/15(a), (j);
- Iowa Code §§126.3(1) and 126.10(1)(a), (j);
- Kentucky Statutes §§217.065(1), (10) and 217.175(1);
- Maryland Code, Health–General §§21-217(b)(1), (6) and 21-256(1);
- Massachusetts General Laws chapter 94 §§187 and 190;
- Minnesota Statutes §§151.34(1) and 151.36(1);
- Missouri Statutes §§196.100(1) and 196.015(1);
- Montana Code §§50-31-306(1)(a), (l) and 50-31-501(1);

- Nebraska Revised Statutes §§71-2470(1) and 71-2481;
- Nevada Statutes §§585.410, 585.470, and 585.520(1);
- New Hampshire Revised Statutes §§146:1(I) and 146:6(I), (X);
- New Mexico Statutes §§26-1-3(A) and 26-1-11(A)(1), (G);
- New York Education Law §§6811 and 6815;
- North Dakota Century Code §§19-02.1-02(1) and 19-02.1-14(1), (11);
- Ohio Code §§3715.52(A)(1) and 3715.64(A)(1), (11);
- Oklahoma Statutes title 63 §§1-1402(a) and 1-1409(a), (j);
- Title 35, Pennsylvania Statutes §§780-108(1), (10) and 780-113(a)(1);
- Title 21, Rhode Island General Laws §§21-3-3(1) and 21-3-15(a)(1), (10);
- South Carolina Code §§39-23-40(a), (j) and 39-23-80(A)(1);
- South Dakota Code §§39-15-5 and 39-15-10;
- Title 18, Vermont Statutes §§4052(1) and 4064(1), (10);
- Virginia Code §§54.1-3457(1) and 54.1-3462(1), (8);
- West Virginia Code §16-7-1; and
- Wyoming Statutes §§35-7-111(a)(i)–(iv), (vi) and 35-7-116.

862. Defendants further breached their duty of care and were negligent in that while representing carcinogenic Ranitidine-Containing Products as safe, Defendants failed to employ manufacturing methods that ensured Ranitidine-Containing Products met the quality and purity characteristics they purported to possess, thereby manufacturing, repackaging, offering for sale, selling, delivering, and/or holding adulterated drugs in violation of 21 U.S.C. §§331 and 351(a)(2)(B) and the following parallel state statutes:

- Alabama Code §§20-1-24 and 20-1-27(1);
- Alaska Statutes §17.20.290(a)(1);

- Arizona Statutes §§32-1965(1), (2) and 32-1966(3);
- Arkansas Code §20-56-215(1);
- California Health and Safety Code §§111295 and 111400;
- Colorado Statutes §§25-5-403(1)(a),(b) and 25-5-414(1)(c);
- Title 16, Delaware Code §§3302 and 3303(2);
- District of Columbia Code §48-702(2);
- Florida Statutes §§499.005(1) and 499.006(3);
- Georgia Code §26-3-3(1);
- Hawaii Revised Statutes §§328-6(1) and 328-14(1)(B)(ii);
- Idaho Code §37-115(a);
- Chapter 410, Illinois Statutes §§620/3.1 and 620/14(a)(2)(B);
- Iowa Code §§126.3(1) and 126.9(1)(c);
- Kentucky Statutes §217.175(1);
- Maryland Code, Health–General §§21-216(c)(5)(2) and 21-256(1);
- Massachusetts General Laws chapter 94 §§186 and 190;
- Minnesota Statutes §§151.34(1) and 151.35(1);
- Missouri Statutes §196.015(1);
- Montana Code §§50-31-305(3) and 50-31-501(1);
- Nebraska Revised Statutes §§71-2461(2) and 71-2481;
- Nevada Statutes §585.520(1);
- New Hampshire Revised Statutes §§146:1(I) and 146:4(V);
- New Mexico Statutes §§26-1-3(A) and 26-1-10(A);
- New York Education Law §6811;
- North Dakota Century Code §§19-02.1-02(1) and 19-02.1-13(3);

- Ohio Code §3715.52(A)(1);
- Oklahoma Statutes title 63 §1-1402(a);
- Title 35, Pennsylvania Statutes §780-113(a)(1);
- Title 21, Rhode Island General Laws §21-3-3(1);
- South Carolina Code §§39-23-30(a)(2)(B) and 39-23-80(A)(1);
- South Dakota Code §§39-15-3 and 39-15-10;
- Title 18, Vermont Statutes §4052(1);
- Virginia Code §54.1-3457(1);
- West Virginia Code §§16-7-1 and 16-7-2(a)(3); and
- Wyoming Statutes §§35-7-111(a)(i)–(iv), (vi) and 35-7-116.

863. Defendants' duties and standards of conduct as set forth in the above-mentioned statutes parallel their common-law duty to exercise ordinary and reasonable care in the manufacture, handling, sale, and labeling of Ranitidine-Containing Products.

864. The above-mentioned statutes were designed to bolster consumer protection and supplement common-law liability for manufacturers, distributors, and sellers of adulterated or misbranded drugs, in order to protect pharmaceutical users and consumers and the general public against harm caused by purchasing and using drugs that are unreasonably dangerous for their recommended and suggested use.

865. Plaintiffs and Class members, as purchasers and consumers of adulterated and misbranded Ranitidine-Containing Products, are within the specific class of persons that the above-mentioned statutes were designed to protect.

866. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming the carcinogenic NDMA poison when using the purportedly safe

Ranitidine-Containing Products as recommended, labeled, and suggested – is that which the above-mentioned statutes contemplate and were designed to prevent.

867. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly labeled and manufactured Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence *per se* and/or evidence of Defendants' negligence toward Plaintiffs and Class members.

868. Additionally, Defendants breached their duty of care by failing to follow current cGMPs in the storing, handling, and warehousing of Ranitidine-Containing Products, thereby increasing the risk that the drugs would produce NDMA during storage and/or transport, in that Defendants failed to ensure that Ranitidine-Containing Products were stored, handled, and warehoused under appropriate conditions of temperature, humidity, and light so that their identity, strength, quality, and purity was not adversely affected, in violation of the cGMPs set forth in 21 C.F.R. §211.142(b).

869. The unreasonable risk of danger posed by Ranitidine-Containing Products due to their ability to transform into the carcinogenic compound NDMA existed at the time the drugs left Defendants' possession and control.

870. Defendants' failure to inform physicians, users, and consumers of the unreasonable danger posed by Ranitidine-Containing Products rendered any other warning related to the drugs inadequate and made them defective and unfit for any foreseeable use.

871. No ordinary, reasonably prudent user or consumer would expect or contemplate that Ranitidine-Containing Products expose users to the carcinogenic NDMA poison when used as directed and intended.

872. Plaintiffs and Class members, who at all relevant times used Ranitidine-Containing Products as Defendants intended or reasonably anticipated, were unaware of the nature and extent of the risks Ranitidine-Containing Products posed and had no reason to realize the drugs' dangerous conditions.

873. Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and Class members would suffer injuries as a natural and probable result of Defendants' failure to exercise due care in the manufacturing, marketing, labeling, distribution, warning, and sale of Ranitidine-Containing Products.

874. At all relevant times, Defendants could have reasonably adopted available and feasible alternative designs for Ranitidine-Containing Products that would have reduced the risk of injury to others, including Plaintiffs and Class members, without undue cost or interference with the product's performance.

875. No reasonably prudent manufacturer in Defendants' position and with Defendants' knowledge of Ranitidine-Containing Products' carcinogenic properties would decline to warn foreseeable users about Ranitidine-Containing Products' inherent risks or continue designing, manufacturing, distributing, selling, promoting, manufacturing, and marketing Ranitidine-Containing Products to have such inherently and unreasonably dangerous characteristics.

876. But for Defendants' negligent acts, Plaintiffs and Class members would not have purchased or consumed Ranitidine-Containing Products.

877. Had Defendants exercised due care to warn prescribers of Ranitidine-Containing Products' unreasonable danger rather than misrepresented and conceal Ranitidine-Containing Products' risks, Plaintiffs' and Class members' physicians would not have prescribed them and Plaintiffs and Class members would have avoided injury.

878. Had Defendants exercised due care to warn OTC users and consumers, including Plaintiffs and Class members, of Ranitidine-Containing Products' unreasonable danger rather than misrepresent and conceal Ranitidine-Containing Products' risks, Plaintiffs and Class members would have read and heeded to the warnings, learned of the risks, and not purchased or consumed Ranitidine-Containing Products, and therefore would have avoided injury.

879. Defendants' negligence was a direct, contributing, and substantial factor in Plaintiffs' and Class members' injuries.

880. As a direct and proximate result of Defendants' failure to exercise ordinary and reasonable care in designing, manufacturing, distributing, and testing Ranitidine-Containing Products so that the products would be reasonably safe for their foreseeable use, Plaintiffs and Class members have been injured. They purchased and ingested Ranitidine-Containing Products that were unsafe for human consumption as a result of Defendants' failures. Had Defendants exercised due care to design, manufacture, distribute, and test a reasonably safe product, Plaintiffs and Class members would not have purchased or used the Ranitidine-Containing Products that exposed them to the carcinogenic NDMA poison.

881. As a direct and proximate result of Defendants' failure to exercise ordinary and reasonable care to provide adequate warnings of Ranitidine-Containing Products' risks, Plaintiffs and Class members have been injured. Plaintiffs and Class members purchased Ranitidine-Containing Products that are unsafe for human consumption as a result of Defendants' misrepresentations, omissions, and concealment of and/or failure to timely disclose the dangerous safety and quality issues associated with the product caused by Defendants' conduct. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased or used Ranitidine-Containing Products.

882. As a direct and proximate result of Defendants' negligent conduct, Plaintiffs and Class members have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

883. Additionally, Defendants' negligence directly and proximately caused Plaintiffs and Class members to: (a) be subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustain a significantly increased risk of developing various types of serious and potentially deadly cancers.

884. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and Class members have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 6
Battery
(Against All Defendants)

885. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

886. This cause of action is brought on behalf of the Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming Classes (collectively for the purposes of this section, the "Class") against all Defendants.

887. The Connecticut Class brings this count pursuant to the Connecticut Products Liability Act, Conn. Gen. Stat. §52-572m, *et seq*.

888. The Oregon Class brings this count pursuant to Oregon Revised Statutes §30.900, *et seq*.

889. The Puerto Rico Class brings this action pursuant to Article 1802 of the Puerto Rico Civil Code, 31 L.P.R.A. §5141.

890. As the designers, manufacturers, marketers, sellers, and distributors of Ranitidine-Containing Products, Defendants intentionally, deliberately, and recklessly engaged in acts that constituted and resulted in an unconsented, harmful, and offensive touching of Plaintiffs and Class members, specifically causing carcinogenic NDMA to come into unconsented, harmful, and offensive contact with Plaintiffs' and Class members' bodies.

891. Plaintiffs and Class members used Ranitidine-Containing Products, which, unbeknownst to them, contained excessive levels of cancer-causing NDMA.

892. Defendants intentionally, deliberately, and recklessly acted to cause Plaintiffs and Class members to consume and come into unconsented, harmful, and offensive contact with the cancer-causing NDMA compound through pervasively and deliberately marketing, promoting, advertising, distributing, selling, and encouraging the use of Ranitidine-Containing Products as safe while concealing the fact that the products exposed users to carcinogenic NDMA.

893. By intentionally, deliberately, and recklessly encouraging and inducing Plaintiffs and Class members to use Ranitidine-Containing Products for personal consumption, Defendants intended, desired, and knew and believed to a substantial certainty that the products and the carcinogenic NDMA they produced would touch and come into unconsented, harmful, and offensive contact with Plaintiffs' and Class members' bodies and internal organs in a harmful and

offensive manner and at excessive levels and thereby cause subcellular and genetic injuries and an increased risk of developing cancer.

894. Defendants' intentional, deliberate, and reckless promotion, advertisement, marketing, distribution, and sale of Ranitidine-Containing Products did, in fact, cause an intentional, unconsented, harmful, and offensive contact with Plaintiffs and Class members in that Defendants' acts caused Plaintiffs and Class members to unknowingly ingest into their bodies harmful, carcinogenic NDMA by consuming Ranitidine-Containing Products exactly as Defendants intended and instructed, in an affront to Plaintiffs' and Class members' reasonable senses of bodily integrity and personal dignity.

895. Defendants' act of intentionally and recklessly touching Plaintiffs' and Class members' bodies with Ranitidine-Containing Products and the carcinogenic NDMA they contained caused harm and physical impairment to Plaintiffs and Class members in that it resulted in subcellular and genetic injuries and increased the risk of cancer.

896. Defendants' act of intentionally and recklessly touching Plaintiffs' and Class members' bodies with Ranitidine-Containing Products was offensive in that a reasonable person would take offense to unconsented bodily contact with known carcinogens.

897. At all relevant times, Defendants knew that Plaintiffs and Class members reasonably and mistakenly believed they were using a product that was reasonably safe for human consumption when used as Defendants intended and directed.

898. Because Defendants intentionally, actively, and recklessly concealed Ranitidine-Containing Products' inherently dangerous and cancer-causing properties, Plaintiffs and Class members did not know of those properties and, thus, could not and did not consent to coming into bodily contact with the carcinogenic NDMA compound contained in Defendants' products.

899. If Defendants had not intentionally, deliberately, and recklessly distributed, sold, advertised, marketed, and promoted the consumption of Ranitidine-Containing Products while willfully concealing the drugs' cancer-causing properties, Plaintiffs and Class members would not have introduced into their system or otherwise come into contact with the unreasonably unsafe product.

900. Defendants willfully and tortiously battered Plaintiffs and Class members.

901. Defendants intended, knew, and should have known to a substantial certainty, that their conduct alleged herein regarding their willful and pervasive distribution, selling, advertising, marketing, misrepresenting, and encouraging use of Ranitidine-Containing Products while knowing of and intentionally concealing the drugs' unreasonably dangerous components – thereby causing Plaintiffs and Class members to ingest cancer-causing NDMA without their consent – was offensive, harmful, and an affront to Plaintiffs' and Class members' reasonable senses of human and personal dignities.

902. Coming into bodily contact with carcinogenic NDMA offended Plaintiffs' and Class members' reasonable senses of human and personal dignities in that it violated Plaintiffs' and Class members' interests in keeping toxic and carcinogenic substances away from and out of their bodies.

903. As a foreseeable, proximate, and direct result of Defendants' actions, Plaintiffs and Class members have each suffered a battery and been injured and damaged, including as otherwise set forth in this Complaint and by invasion of their privacy and bodily integrity without their consent, cellular and genetic injuries, an increased risk of developing cancer, severe emotional stress and anxiety, harm to their human dignity, and corresponding damages therefrom.

904. Accordingly, Defendants' battery directly and proximately caused Plaintiffs and Class members to: (a) be subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustain a significantly increased risk of developing various types of serious and potentially deadly cancers.

905. As a direct and proximate result of Defendants' actions, Plaintiffs and Class members have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1. Causes of Action Brought on Behalf of the Alabama Class

COUNT 7
Breach of Express Warranty
(Ala. Code §7-2-313)
(Against All Defendants)

906. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

907. This cause of action is brought on behalf of the Alabama Class (for the purpose of this section, "Class") against all Defendants.

908. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ala. Code §7-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Ala. Code §7-2-313.

909. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ala. Code §7-2-313.

910. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or

promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

911. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

912. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

913. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and

> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

914. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

915. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

916. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 8
Breach of Implied Warranty
(Ala. Code §7-2-314)
(Against All Defendants)

917. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

918. This cause of action is brought on behalf of the Alabama Class (for the purpose of this section, "Class") against all Defendants.

919. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

920. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ala. Code §7-2-314.

921. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

922. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

923. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

924. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

925. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

926. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 9
Violation of the Alabama Deceptive Trade Practices Act
(Ala. Code §8-19-1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

927. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

928. This cause of action is brought on behalf of the Alabama Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

929. Defendants, Plaintiffs, and the Class members are "person[s]" within the meaning of Ala. Code §8-19-3(5).

930. Plaintiffs and the Class members are "consumer[s]" within the meaning of Ala. Code §8-19-3(2).

931. The Ranitidine-Containing Products are "goods" within the meaning of Ala. Code §8-19-3(3).

932. Defendants were and are engaged in "trade or commerce" within the meaning of Ala. Code §8-19-3(8).

933. The Alabama Deceptive Trade Practices Act ("Alabama DTPA") prohibits "deceptive acts or practices in the conduct of any trade or commerce." Ala. Code §8-19-5.

934. The Alabama DTPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have" (Ala. Code §8-19-5(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Ala. Code §8-19-5(7));

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Ala. Code §8-19-5(9)); and

(d) "[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce" (Ala. Code §8-19-5(27)).

935. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Alabama DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

936. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Alabama DTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

937. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

938. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

939. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

940. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

941. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Alabama DTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from

Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

942. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Alabama DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

943. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

944. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in *In re Zantac (Ranitidine) Products Liability Litigation*, No. 9:20-md-02924-RLR (S.D. Fla.) ("MDL 2924") sent a notice letter pursuant to Ala. Code §8-19-10(e) to Defendants.

Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

945. As a result of Defendants' violations of the Alabama DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Alabama DTPA.

COUNT 10
Products Liability/Failure to Warn
Alabama Extended Manufacturer's Liability Doctrine
(Against All Defendants)

946. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

947. This cause of action is brought on behalf of the Alabama Class (for the purpose of this section, "Class") against all Defendants.

948. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

949. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members

of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

950. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

951. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

952. The Ranitidine-Containing Products were not properly prepared.

953. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

954. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

955. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the

dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

956. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e*., the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

957. At all relevant times, the failure to provide these adequate warnings and/or instructions made the Defendants' Ranitidine-Containing Products unreasonably dangerous.

958. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

959. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

960. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

961. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

962. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

963. 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.

964. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class 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-Containing Products; continued to aggressively promote the efficacy of their 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-Containing Products.

965. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

966. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

967. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

968. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

969. Accordingly, Plaintiffs and members of the Class would not have (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular

damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

970. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 11
Alabama Extended Manufacturer's Liability Doctrine/Manufacturing Defect
(Against Brand-Name Manufacturer Defendants
and Generic Manufacturer Defendants)

971. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

972. This cause of action is brought on behalf of the Alabama Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

973. At all times herein mentioned, the Manufacturer Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

974. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by the Manufacturer Defendants.

975. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

976. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by the Manufacturer Defendants.

977. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that the Manufacturer Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

978. The Ranitidine-Containing Products were not properly prepared.

979. The Manufacturer Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

980. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

981. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of the Manufacturer Defendants' manufacturing defects, which included but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products;

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

982. The manufacturing defects in the Manufacturer Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

983. As a direct and proximate result of the Manufacturing Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

984. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Manufacturer Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

985. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

COUNT 12
Strict Products Liability/Design Defect
(Against All Defendants)

986. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

987. This cause of action is brought on behalf of the Alabama Class (for the purpose of this section, "Class") against all Defendants.

988. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of these Defendants. At all relevant times, the Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

989. At all relevant times, the Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

990. At all relevant times, these Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by the Defendants. At all relevant times, these Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a

consumer market. These Defendants were at all relevant times involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

991. The Ranitidine-Containing Products were not properly prepared.

992. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

993. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

994. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

995. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

996. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) Exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

997. Plaintiffs and the Class members used and/or were exposed to the Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

998. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of the Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

999. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1000. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1001. The harm caused by the Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. The Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and these Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1002. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the Defendants' Ranitidine-Containing Products. For example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1003. The defects in the Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1004. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1005. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1006. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2. Causes of Action Brought on Behalf of the Alaska Class

COUNT 13
Breach of Express Warranty
(Alaska Stat. Ann. §45.02.313)
(Against All Defendants)

1007. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1008. This cause of action is brought on behalf of the Alaska Class (for the purpose of this section, "Class") against all Defendants.

1009. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Alaska Stat. Ann. §45.02.313 and "sellers" of Ranitidine-Containing Products within the meaning of Alaska Stat. Ann. §45.02.313.

1010. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Alaska Stat. Ann. §45.02.313.

1011. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1012. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1013. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1014. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1015. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1016. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1017. Plaintiffs and the Class members gave Defendants reasonable notice of their breaches of express warranty and an opportunity to cure such breaches or, in the alternative, were not required to do so because such an opportunity would be unnecessary and futile given that Defendants are unable to cure the defect in Ranitidine-Containing Products.

1018. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 14
Breach of Implied Warranty
(Alaska Stat. Ann. §45.02.314)
(Against All Defendants)

1019. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1020. This cause of action is brought on behalf of the Alaska Class (for the purpose of this section, "Class") against all Defendants.

1021. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1022. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Alaska Stat. Ann. §45.02.314.

1023. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1024. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1025. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1026. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1027. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1028. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 15
Violation of the Alaska Unfair Trade Practices and Consumer Protection Act
(Alaska Stat. Ann. §45.50.471, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1029. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1030. This cause of action is brought on behalf of the Alaska Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1031. Plaintiffs and the Class members are "consumer[s]" within the meaning of Alaska Stat. Ann. §45.50.561(a)(4).

1032. The Alaska Unfair Trade Practices and Consumer Protection Act ("Alaska CPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce." Alaska Stat. Ann. §45.50.471(a).

1033. The Alaska CPA makes unlawful specific acts, including:

(a) "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Alaska Stat. Ann. §45.50.471(b)(4));

(b) "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Alaska Stat. Ann. §45.50.471(b)(6));

(c) "advertising goods or services with intent not to sell them as advertised" (Alaska Stat. Ann. §45.50.471(b)(8));

(d) "engaging in any other conduct creating a likelihood of confusion or of misunderstanding and that misleads, deceives, or damages a buyer or a competitor in connection with the sale or advertisement of goods or services" (Alaska Stat. Ann. §45.50.471(b)(11)); and

(e) "using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods or services whether or not a person has in fact been misled, deceived, or damaged" (Alaska Stat. Ann. §45.50.471(b)(12)).

1034. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1035. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Alaska CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1036. Specifically by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Alaska CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1037. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1038. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1039. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1040. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Alaska CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1041. Plaintiffs and Class members were aggrieved by Defendants' violations of the Alaska CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1042. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1043. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Alaska Stat. Ann. §45.50.535(b)(1) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

1044. As a result of Defendants' violations of the Alaska CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Alaska CPA.

COUNT 16
Strict Products Liability/Failure to Warn
(Against All Defendants)

1045. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1046. This cause of action is brought on behalf of the Alaska Class (for the purpose of this section, "Class") against all Defendants.

1047. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing,

distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1048. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1049. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1050. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1051. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they

knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1052. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1053. Even though Defendants knew or should have known that the Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1054. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1055. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1056. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1057. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1058. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1059. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1060. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1061. 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.

1062. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1063. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1064. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1065. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1066. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1067. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1068. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 17
Strict Product Liability/Manufacturing Defect
(Against All Defendants)

1069. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1070. This cause of action is brought on behalf of the Alaska Class (for the purpose of this section, "Class") against all Defendants.

1071. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1072. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1073. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1074. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1075. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1076. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1077. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1078. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1079. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1080. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1081. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1082. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 18
Strict Products Liability/Design Defect
(Against All Defendants)

1083. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1084. This cause of action is brought on behalf of the Alaska Class (for the purpose of this section, "Class") against all Defendants.

1085. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1086. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1087. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products,

including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1088. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1089. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1090. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1091. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1092. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1093. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1094. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1095. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1096. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1097. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1098. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid

(Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1099. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1100. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1101. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1102. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

3. Causes of Action Brought on Behalf of the Arizona Class

COUNT 19
Breach of Express Warranty
(Ariz. Rev. Stat. Ann. §47-2313)
(Against All Defendants)

1103. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1104. This cause of action is brought on behalf of the Arizona Class (for the purpose of this section, "Class") against all Defendants.

1105. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ariz. Rev. Stat. Ann. §47-2313 and "sellers" of Ranitidine-Containing Products within the meaning of Ariz. Rev. Stat. Ann. §47-2313.

1106. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ariz. Rev. Stat. Ann. §47-2313.

1107. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1108. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1109. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1110. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the

Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1111. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1112. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1113. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 20
Breach of Implied Warranty
(Ariz. Rev. Stat. Ann. §47-2314)
(Against All Defendants)

1114. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1115. This cause of action is brought on behalf of the Arizona Class (for the purpose of this section, "Class") against all Defendants.

1116. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1117. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ariz. Rev. Stat. Ann. §47-2314.

1118. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1119. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1120. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1121. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1122. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1123. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 21
Violation of the Arizona Consumer Fraud Act
(Ariz. Rev. Stat. Ann. §44-1521, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1124. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1125. This cause of action is brought on behalf of the Arizona Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1126. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ariz. Rev. Stat. Ann. §44-1521(6).

1127. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Ariz. Rev. Stat. Ann. §44-1521(5).

1128. The Arizona Consumer Fraud Act ("Arizona CFA") prohibits "[t]he act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, … misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale … of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby." Ariz. Rev. Stat. Ann. §44-1522(A).

1129. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Arizona CFA by recklessly, wantonly, knowingly, and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1130. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Arizona CFA.

1131. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1132. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein,

had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1133. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1134. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

1135. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1136. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Arizona CFA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the

Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1137. Plaintiffs and Class members were aggrieved by Defendants' violations of the Arizona CFA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1138. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1139. As a result of Defendants' violations of the Arizona CFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Arizona CFA.

COUNT 22
Strict Products Liability/Failure to Warn
(Against All Defendants)

1140. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1141. This cause of action is brought on behalf of the Arizona Class (for the purpose of this section, "Class") against all Defendants.

1142. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1143. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1144. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1145. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1146. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1147. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1148. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

1149. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1150. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1151. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1152. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1153. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1154. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1155. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1156. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1157. 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.

1158. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1159. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1160. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1161. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1162. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1163. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1164. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 23
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1165. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1166. This cause of action is brought on behalf of the Arizona Class (for the purpose of this section, "Class") against all Defendants.

1167. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1168. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1169. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1170. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1171. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their

manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1172. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1173. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1174. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

1175. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1176. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1177. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1178. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1179. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 24
Strict Products Liability/Design Defect
(Against All Defendants)

1180. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1181. This cause of action is brought on behalf of the Arizona Class (for the purpose of this section, "Class") against all Defendants.

1182. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1183. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1184. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

1185. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1186. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1187. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1188. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1189. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1190. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1191. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1192. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1193. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1194. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1195. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1196. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1197. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1198. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1199. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1200. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

4. Causes of Action Brought on Behalf of the Arkansas Class

COUNT 25
Breach of Express Warranty
(Ark. Code Ann. §4-2-313)
(Against All Defendants)

1201. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1202. This cause of action is brought on behalf of the Arkansas Class (for the purpose of this section, "Class") against all Defendants.

1203. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ark. Code Ann. §4-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Ark. Code Ann. §4-2-313.

1204. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ark. Code Ann. §4-2-313.

1205. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or

promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1206. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1207. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1208. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and

> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1209. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1210. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1211. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 26
Breach of Implied Warranty
(Ark. Code Ann. §4-2-314)
(Against All Defendants)

1212. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1213. This cause of action is brought on behalf of the Arkansas Class (for the purpose of this section, "Class") against all Defendants.

1214. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1215. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ark. Code Ann. §4-2-314.

1216. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1217. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1218. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1219. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1220. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1221. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 27
Violation of the Arkansas Deceptive Trade Practices Act
(Ark. Code Ann. §4-88-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1222. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1223. This cause of action is brought on behalf of the Arkansas Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1224. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ark. Code Ann. §4-88-102(5).

1225. The Ranitidine-Containing Products are "[g]oods" within the meaning of Ark. Code Ann. §4-88-102(4).

1226. The Arkansas Deceptive Trade Practices Act ("Arkansas DTPA") prohibits "[d]eceptive and unconscionable trade practices." Ark. Code Ann. §4-88-107(a).

1227. The Arkansas DTPA makes unlawful specific acts, including:

(a) "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services or as to whether goods are original or new or of a particular standard, quality, grade, style, or model" (Ark. Code Ann. §4-88-107(a)(1));

(b) "[a]dvertising the goods or services with the intent not to sell them as advertised" (Ark. Code Ann. §4-88-107(a)(3)); and

(c) "[e]ngaging in any other unconscionable, false, or deceptive act or practice in business, commerce, or trade" (Ark. Code Ann. §4-88-107(a)(10)).

1228. The Arkansas DTPA also prohibits the following when utilized in connection with the sale or advertisement of any goods: "(1) The act, use, or employment by any person of any deception, fraud, or false pretense; [or] (2) [t]he concealment, suppression, or omission of any material fact with intent that others rely upon the concealment, suppression, or omission . . . ." Ark. Code Ann. §4-88-108(a).

1229. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Arkansas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1230. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Arkansas DTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(a) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(b) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(c) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1231. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1232. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1233. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1234. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1235. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Arkansas DTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members,

and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1236. Plaintiffs and the Class members were aggrieved by Defendants' violations of Arkansas DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1237. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1238. As a result of Defendants' violations of the Arkansas DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Arkansas DTPA.

COUNT 28
Strict Products Liability/Failure to Warn
Arkansas Product Liability Act of 1979
(Against All Defendants)

1239. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1240. This cause of action is brought on behalf of the Arkansas Class (for the purpose of this section, "Class") against all Defendants.

1241. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1242. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1243. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1244. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1245. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1246. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1247. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1248. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1249. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1250. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1251. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1252. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1253. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1254. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1255. 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.

1256. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1257. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1258. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1259. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1260. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1261. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1262. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 29
Strict Products Liability/Manufacturing Defect
Arkansas Product Liability Act of 1979
(Against All Defendants)

1263. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1264. This cause of action is brought on behalf of the Arkansas Class (for the purpose of this section, "Class") against all Defendants.

1265. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1266. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1267. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1268. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1269. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1270. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1271. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1272. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1273. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1274. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1275. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1276. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 30
Strict Products Liability/Design Defect
Arkansas Product Liability Act of 1979
(Against All Defendants)

1277. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1278. This cause of action is brought on behalf of the Arkansas Class (for the purpose of this section, "Class") against all Defendants.

1279. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1280. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1281. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1282. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1283. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1284. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1285. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1286. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1287. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1288. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1289. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1290. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1291. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1292. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1293. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1294. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1295. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1296. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5. Causes of Action Brought on Behalf of the California Class

COUNT 31
Breach of Express Warranty
(Cal. Com. Code §2313)
(Against All Defendants)

1297. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1298. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against all Defendants.

1299. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Cal. Com. Code §2313 and "sellers" of Ranitidine-Containing Products within the meaning of Cal. Com. Code §2313.

1300. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Cal. Com. Code §2313.

1301. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1302. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1303. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1304. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

1305. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1306. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1307. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1308. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 32
Breach of Implied Warranty
(Cal. Com. Code §2314)
(Against All Defendants)

1309. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1310. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against all Defendants.

1311. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1312. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Cal. Com. Code §2314.

1313. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1314. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1315. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1316. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1317. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1318. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 33
Violation of the California Unfair Competition Law
(Cal. Bus. & Prof. Code §17200, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1319. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1320. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1321. Defendants, Plaintiffs, and the Class members are "persons" within the meaning of Cal. Bus. & Prof. Code §17201.

1322. Cal. Bus. & Prof. Code §17200 ("California UCL") prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

1323. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the California UCL by knowingly and intentionally misrepresenting, omitting,

concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.

1324. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the California UCL. These acts also constitute "fraudulent" business acts and practices under the California UCL in that Defendants' conduct is false, misleading, and has a tendency to deceive the Class and the general public.

1325. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1326. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1327. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1328. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1329. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the California UCL in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1330. Moreover, Defendants engaged in "unlawful" business acts or practices by violating both federal and California laws, including: the federal RICO statute, 18 U.S.C. §1962(c)-(d); adulteration and misbranding provisions under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§331(a), (c), (g), 351(a)(2)(B), (b), (d), 352(a)(1), (c), (e)(1)(A)(ii), (f)-(g), (i)(2)-(3), (j), (n), (p); Good Manufacturing Practices, 21 C.F.R. 210.1(a), 211.142(b); adulteration and misbranding provisions under the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE §§111260, 111280, 111290, 111295, 111305, 111330, 111345, 111355(a)(3), 111360(b), 111375, 111380, 111395(a)-(b), 111400, 111440, 111445, 111450; the Consumer Legal Remedies Act, Cal. Civ. Code §1750; and the California FAL, Cal. Bus. & Prof. Code §17500, as alleged herein.

1331. Defendants conduct also consitutes "unfair" business acts or practies. Under the balancing test, the determination of whether a business practice is "unfair" involves examining the practice's impact on its alleged victim, balanced against the reasons, justifications, and motives of the alleged wrongdoer. Here, Defendants' practice of misrepresenting, omitting, concealing, and failing to disclose that their Ranitidine-Containing Products expose consumers to unsafe levels of NDMA, a potent carcinogen, when used or ingested, caused a substantial injury to Plaintiffs and Class members by putting them at an increased risk of developing serious or deadly forms of cancer, causing them to pay for a product they otherwise would not have purchased, depriving them of benefit of their bargain, and/or causing them to suffer out-of-pocket losses. On the other hand, Defendants' misrepresentations, omissions, concealments, and failures to disclose the truth regarding the inherently defective and unreasonably dangerous nature of their Ranitidine-Containing Products have no apparent utility.

1332. Additionally, Defendants' conduct was "unfair" under the tethering test, in that it violated the federal RICO statute, 18 U.S.C. §1962(c)-(d); adulteration and misbranding provisions under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§331(a), (c), (g), 351(a)(2)(B), (b), (d), 352(a)(1), (c), (e)(1)(A)(ii), (f)-(g), (i)(2)-(3), (j), (n), (p); Good Manufacturing Practices, 21 C.F.R. 210.1(a), 211.142(b); adulteration and misbranding provisions under the Sherman Food, Drug, and Cosmetic Laws, Cal. Health & Safety Code §§111260, 111280, 111290, 111295, 111305, 111330, 111345, 111355(a)(3), 111360(b), 111375, 111380, 111395(a)-(b), 111400, 111440, 111445, 111450; the Consumer Legal Remedies Act, *see* Cal. Civ. Code §1760; and the California FAL, Cal. Bus. & Prof. Code §17500, which reflect the United States' and California's policy of protecting consumers against unfair and deceptive business practices and adulterated and misbranded drugs.

1333. Plaintiffs and the Class members were aggrieved by Defendants' violations of the California UCL because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1334. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1335. Pursuant to Cal. Bus. & Prof. Code §§17200 and 17203, Plaintiffs and Class members seek an order providing restitution and disgorgement of all profits relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

COUNT 34
Violation of the California False Advertising Law
(Cal. Bus. & Prof. Code §17500, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1336. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1337. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1338. Defendants, Plaintiffs, and the Class members are "persons" within the meaning of Cal. Bus. & Prof. Code §17506.

1339. The California False Advertising Law ("California FAL") prohibits "any person, . . . corporation . . . or any employee thereof with intent directly or indirectly to dispose of real or personal property . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated . . . before the public in this state or from this state before the public in any state, in any newspaper or other publication, or any advertising device, . . . or in any other manner or means whatever, including over the internet, any statement . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof. Code §17500.

1340. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the California FAL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1341. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the California FAL, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1342. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1343. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1344. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1345. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had

concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1346. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the California FAL in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1347. Plaintiffs and the Class members were aggrieved by Defendants' violations of the California FAL because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1348. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1349. As a result of Defendants' violations of the California FAL, as alleged herein, Plaintiffs and the Class members seek an order providing restitution and disgorgement of all profits relating to the above-described business acts or practices, and other appropriate relief, including injunctive and declaratory relief as may be appropriate under the California FAL.

COUNT 35
Violation of the California Consumers Legal Remedies Act
(Cal. Civ. Code §1750, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1350. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1351. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1352. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Cal. Civ. Code §1761(c).

1353. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Cal. Civ. Code §1761(d).

1354. The Ranitidine-Containing Products are "[g]oods" within the meaning of Cal. Civ. Code §1761(a).

1355. The California Consumers Legal Remedies Act ("California CLRA") prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or that results in the sale or lease of goods or services to any consumer." Cal. Civ. Code §1770(a).

1356. The California CLRA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Cal. Civ. Code §1770(a)(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Cal. Civ. Code §1770(a)(7));

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Cal. Civ. Code §1770(a)(9)); and

(d) "[r]epresenting that the subject of a transaction has been supplied in accordance with a previous representation when it has not" (Cal. Civ. Code §1770(a)(16)).

1357. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the California CLRA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1358. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the California CLRA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1359. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1360. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1361. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1362. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1363. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the California CLRA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from

Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1364. Plaintiffs and the Class members were aggrieved by Defendants' violations of the California CLRA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1365. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1366. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Cal. Civ. Code §1782 to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

1367. Pursuant to Cal. Civ. Code §1780(a), Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding damages and any other just and proper relief available under the California CLRA. Under Cal. Civ. Code §1780(b), Plaintiffs seek an additional award against Defendants of up to $5,000 for each Class member who qualifies as a "senior citizen" or "disabled person" under the California CLRA. Defendants knew or should have known that their conduct was directed to one or more Class members who are senior citizens or disabled persons. Defendants' conduct caused one or more of these senior citizens or disabled persons to suffer a substantial loss of property set aside for retirement or for personal or family care and maintenance, or assets essential to the health or welfare of the senior citizen or disabled person. One or more Class members who are senior citizens or disabled persons are substantially more vulnerable to Defendants' conduct because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and each of them suffered substantial physical, emotional, or economic damage resulting from Defendants' conduct.

COUNT 36
Strict Products Liability/Failure to Warn
(Against All Defendants)

1368. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1369. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against all Defendants.

1370. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they

do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1371. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1372. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1373. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1374. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1375. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1376. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1377. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1378. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1379. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used

as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1380. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1381. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1382. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1383. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1384. 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.

1385. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1386. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1387. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1388. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1389. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1390. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1391. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 37
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1392. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1393. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against all Defendants.

1394. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1395. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1396. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1397. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1398. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1399. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1400. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1401. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the

utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1402. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1403. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1404. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1405. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 38
Strict Products Liability/Design Defect

1406. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1407. This cause of action is brought on behalf of the California Class (for the purpose of this section, "Class") against all Defendants.

1408. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of these Defendants. At all relevant times, the Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1409. At all relevant times, the Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1410. At all relevant times, these Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by the Defendants. At all relevant times, these Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a

consumer market. These Defendants were at all relevant times involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1411. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1412. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1413. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1414. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1415. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1416. Plaintiffs and the Class members used and/or were exposed to the Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1417. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of the Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1418. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1419. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1420. The harm caused by the Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. The Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and these Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1421. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the Defendants' Ranitidine-Containing Products. For example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1422. The defects in the Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1423. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1424. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1425. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

6. Causes of Action Brought on Behalf of the Colorado Class

COUNT 39
Breach of Express Warranty
(Colo. Rev. Stat. Ann. §4-2-313)
(Against Defendants)

1426. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1427. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against all Defendants.

1428. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Colo. Rev. Stat. Ann. §4-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Colo. Rev. Stat. Ann. §4-2-313.

1429. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Colo. Rev. Stat. Ann. §4-2-313.

1430. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1431. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1432. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1433. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1434. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1435. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1436. Plaintiffs and the Class members gave Defendants reasonable notice of their breaches of express warranty and an opportunity to cure such breaches or, in the alternative, were not required to do so because such an opportunity would be unnecessary and futile given that Defendants are unable to cure the defect in Ranitidine-Containing Products.

1437. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 40
Breach of Implied Warranty
(Colo. Rev. Stat. Ann. §4-2-314)
(Against All Defendants)

1438. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1439. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against all Defendants.

1440. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1441. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Colo. Rev. Stat. Ann. §4-2-314.

1442. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1443. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1444. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1445. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1446. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1447. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 41
Violation of the Colorado Consumer Protection Act
(Colo. Rev. Stat. Ann. §6-1-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1448. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1449. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1450. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Colo. Rev. Stat. Ann. §6-1-102(6).

1451. The Colorado Consumer Protection Act ("Colorado CPA") prohibits unfair, unconscionable, and deceptive acts or practices "in the course of the person's business, vocation, or occupation." Colo. Rev. Stat. Ann. §6-1-105(1).

1452. The Colorado CPA makes unlawful specific acts, including:

(a) "[e]ither knowingly or recklessly mak[ing] a false representation as to the source, sponsorship, approval, or certification of goods, services, or property" (Colo. Rev. Stat. Ann. §6-1-105(1)(b));

(b) "[r]epresent[ing] that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another" (Colo. Rev. Stat. Ann. §6-1-105(1)(g));

(c) "[a]dvertis[ing] goods, services, or property with intent not to sell them as advertised" (Colo. Rev. Stat. Ann. §6-1-105(1)(i));

(d) "[f]ails to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction" (Colo. Rev. Stat. Ann. §6-1-105(1)(u)); and

(e) "[e]ither knowingly or recklessly engage[ing] in any unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice" (Colo. Rev. Stat. Ann. §6-1-105(1)(kkk)).

1453. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Colorado CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above. Such conduct was bad faith conduct under the Colorado CPA.

1454. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as

detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Colorado CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce; and

(e) failing to disclose the defective Ranitidine-Containing Products in connection with their sale to the public.

1455. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1456. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1457. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1458. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

1459. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1460. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Colorado CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1461. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Colorado CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not

engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1462. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1463. As a result of Defendants' violations of the Colorado CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Colorado CPA.

COUNT 42
Strict Products Liability/Failure to Warn
(Against All Defendants)

1464. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1465. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against all Defendants.

1466. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Manufacturer Defendants.

1467. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1468. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1469. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1470. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1471. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including

Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1472. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

1473. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1474. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1475. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1476. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used

as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1477. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1478. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1479. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1480. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1481. 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.

1482. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1483. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1484. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1485. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1486. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1487. Accordingly, Plaintiffs and the members of the Class would not have sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1488. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 43
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1489. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1490. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against all Defendants.

1491. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1492. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1493. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1494. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1495. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1496. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1497. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1498. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

1499. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and

treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1500. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1501. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1502. Accordingly, Plaintiffs and the members of the Class would not have sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1503. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 44
Strict Products Liability/Design Defect
(Against All Defendants)

1504. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1505. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against all Defendants.

1506. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1507. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1508. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

1509. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and

expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1510. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1511. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1512. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1513. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1514. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled,

distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1515. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1516. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1517. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1518. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1519. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1520. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1521. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1522. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1523. Accordingly, Plaintiffs and the members of the Class would not have sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1524. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 45
Medical Monitoring
(Against All Defendants)

1525. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1526. This cause of action is brought on behalf of the Colorado Class (for the purpose of this section, "Class") against all Defendants.

1527. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

1528. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning,

sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

1529. Defendants breached these duties by, *inter alia,* failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

1530. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA

when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

1531. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

1532. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

1533. Plaintiffs and members of the Class 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.

1534. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

1535. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

1536. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1537. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

1538. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

1539. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1540. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

1541. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1542. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Causes of Action Brought on Behalf of the Connecticut Class

COUNT 46
Breach of Express Warranty
(Conn. Gen. Stat. Ann. §42a-2-313)
(Against All Defendants)

1543. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1544. This cause of action is brought on behalf of the Connecticut Class (for the purpose of this section, "Class") against all Defendants.

1545. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Conn. Gen. Stat. Ann. §42a-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Conn. Gen. Stat. Ann. §42a-2-313.

1546. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Conn. Gen. Stat. Ann. §42a-2-313.

1547. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or

promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1548. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1549. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1550. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and

Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1551. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1552. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1553. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 47
Breach of Implied Warranty
(Conn. Gen. Stat. Ann. §42a-2-314)
(Against All Defendants)

1554. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1555. This cause of action is brought on behalf of the Connecticut Class (for the purpose of this section, "Class") against all Defendants.

1556. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1557. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Conn. Gen. Stat. Ann. §42a-2-314.

1558. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1559. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1560. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1561. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1562. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1563. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 48
Violation of the Connecticut Unfair Trade Practices Act
(Conn. Gen. Stat. Ann. §42-110a, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1564. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1565. This cause of action is brought on behalf of the Connecticut Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1566. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Conn. Gen. Stat. Ann. §42-110a(3).

1567. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Conn. Gen. Stat. Ann. §42-110a(4).

1568. The Connecticut Unfair Trade Practices Act ("Connecticut UTPA") prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. Ann. §42-110b(a).

1569. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Connecticut UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1570. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Connecticut UTPA.

1571. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1572. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1573. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1574. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1575. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Connecticut UTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1576. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Connecticut UTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1577. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1578. As a result of Defendants' violations of the Connecticut UTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Connecticut UTPA.

COUNT 49
Strict Products Liability/Failure to Warn
(Against All Defendants)

1579. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1580. This cause of action is brought on behalf of the Connecticut Class (for the purpose of this section, "Class") against all Defendants.

1581. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1582. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1583. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1584. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1585. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1586. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1587. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1588. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1589. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1590. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1591. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1592. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1593. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1594. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1595. 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.

1596. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1597. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1598. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1599. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1600. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1601. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1602. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 50
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1603. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1604. This cause of action is brought on behalf of the Connecticut Class (for the purpose of this section, "Class") against all Defendants.

1605. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1606. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1607. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1608. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1609. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1610. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1611. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1612. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1613. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1614. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1615. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1616. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 51
Strict Products Liability/Design Defect
(Against All Defendants)

1617. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1618. This cause of action is brought on behalf of the Connecticut Class (for the purpose of this section, "Class") against all Defendants.

1619. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1620. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1621. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1622. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1623. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1624. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1625. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1626. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1627. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1628. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1629. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1630. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1631. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1632. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1633. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1634. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1635. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1636. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

8. Causes of Action Brought on Behalf of the Delaware Class

COUNT 52
Breach of Express Warranty
(Del. Code Ann. tit. 6, §2-313)
(Against All Defendants)

1637. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1638. This cause of action is brought on behalf of the Delaware Class (for the purpose of this section, "Class") against all Defendants.

1639. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Del. Code Ann. tit. 6, §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Del. Code Ann. tit. 6, §2-313.

1640. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Del. Code Ann. tit. 6, §2-313.

1641. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1642. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1643. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1644. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1645. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1646. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1647. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 53
Breach of Implied Warranty
(Del. Code Ann. tit. 6, §2-314)
(Against All Defendants)

1648. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1649. This cause of action is brought on behalf of the Delaware Class (for the purpose of this section, "Class") against all Defendants.

1650. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiff and the Class and were in the business of selling such products.

1651. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will merchantable and fit for the ordinary purpose for which it would be used. Del. Code Ann. tit. 6, §2-314.

1652. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1653. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1654. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1655. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1656. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1657. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 54
Violation of the Delaware Consumer Fraud Act and Deceptive Trade Practices Act
(Del. Code Ann. tit. 6, §2511, *et seq.*, and §2531, *et. seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1658. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1659. This cause of action is brought on behalf of the Delaware Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1660. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Del. Code Ann. tit. 6, §§2511(7) and 2531(5).

1661. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Del. Code Ann. tit. 6, §2511(6).

1662. The Delaware Consumer Fraud Act ("Delaware CFA") and Delaware Deceptive Trade Practices Act ("Delaware DTPA") prohibit "act[s], use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby," and deceptive practices "in the course of a business, vocation, or occupation." Del. Code Ann. tit. 6, §§2513(a) and 2532(a).

1663. The Delaware DTPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Del. Code Ann. tit. 6, §2532(5));

(b) "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Del. Code Ann. tit. 6, §2532(7));

(c) "[a]dvertis[ing] goods or services with intent not to sell them as advertised" (Del. Code Ann. tit. 6, §2532(9)); and

(d) "[e]ngag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding" (Del. Code Ann. tit. 6, §2532(12)).

1664. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Delaware CFA and Delaware DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1665. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Delaware CFA and Delaware DTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1666. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1667. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class

members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1668. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1669. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1670. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Delaware CFA and Delaware DTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1671. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Delaware CFA and Delaware DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit

to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1672. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1673. As a result of Defendants' violations of the Delaware CFA and Delaware DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Delaware CFA and Delaware DTPA.

1674.

9. Causes of Action Brought on Behalf of the District of Columbia Class

COUNT 55
Breach of Express Warranty
(D.C. Code Ann. §28:2-313)
(Against All Defendants)

1675. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1676. This cause of action is brought on behalf of the District of Columbia Class (for the purpose of this section, "Class") against all Defendants.

1677. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of D.C. Code Ann. §28:2-313 and "sellers" of Ranitidine-Containing Products within the meaning of D.C. Code Ann. §28:2-313.

1678. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of D.C. Code Ann. §28:2-313.

1679. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1680. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1681. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1682. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the

Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1683. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1684. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1685. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 56
Breach of Implied Warranty
(D.C. Code Ann. §28:2-314)
(Against All Defendants)

1686. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1687. This cause of action is brought on behalf of the District of Columbia Class (for the purpose of this section, "Class") against all Defendants.

1688. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1689. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. D.C. Code Ann. §28:2-314.

1690. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1691. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1692. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1693. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1694. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1695. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 57
Violation of the District of Columbia Consumer Protection Procedures Act
(D.C. Code Ann. §28-3901, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1696. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1697. This cause of action is brought on behalf of the District of Columbia Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1698. Defendants, Plaintiffs, and the Class members are "person[s]" within the meaning of D.C. Code Ann. §28-3901(a)(1).

1699. Plaintiffs and the Class members are "consumer[s]" within the meaning of D.C. Code Ann. §28-3901(a)(2).

1700. The Ranitidine-Containing Products are "goods" within the meaning of D.C. Code Ann. §28-3901(a)(7).

1701. Defendants were and are engaged in "trade practice[s]" within the meaning of D.C. Code Ann. §28-3901(a)(6).

1702. The District of Columbia Consumer Protection Procedures Act ("District of Columbia CPPA") prohibits "unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby." D.C. Code Ann. §28-3904.

1703. The District of Columbia CPPA makes unlawful specific acts, including:

(a) "represent[ing] that goods or services have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, benefits, or quantities that they do not have" (D.C. Code Ann. §28-3904(a));

(b) "represent[ing] that goods or services are of particular standard, quality, grade, style, or model, if in fact they are of another" (D.C. Code Ann. §28-3904(d));

(c) "advertis[ing] or offer[ing] goods or services without the intent to sell them or without the intent to sell them as advertised or offered" (D.C. Code Ann. §28-3904(h));

(d) "misrepresent as to a material fact which has a tendency to mislead" (D.C. Code Ann. §28-3904(e));

(e) "fail to state a material fact if such failure tends to mislead" (D.C. Code Ann. §28-3904(f)); and

(f) "[u]se innuendo or ambiguity as to a material fact, which has a tendency to mislead" (D.C. Code Ann. §28-3904(f-1)).

1704. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the District of Columbia CPPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-

Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1705. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the District of Columbia CPPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) using exaggeration and/or failing to state the material facts concerning the Ranitidine-Containing Products in a manner that tended to deceive;

(e) acting in a manner that resulted in a gross disparity between the true value of the Ranitidine-Containing Products and the price paid; and

(f) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1706. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1707. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class

members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1708. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1709. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1710. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the District of Columbia CPPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1711. Plaintiffs and the Class members were aggrieved by Defendants' violations of the District of Columbia CPPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used

for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1712. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1713. As a result of Defendants' violations of the District of Columbia CPPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the District of Columbia CPPA.

COUNT 58
Strict Products Liability/Failure to Warn
(Against All Defendants)

1714. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1715. This cause of action is brought on behalf of the District of Columbia Class (for the purpose of this section, "Class") against all Defendants.

1716. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they

do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1717. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1718. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1719. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1720. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1721. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1722. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1723. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1724. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1725. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used

as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1726. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1727. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1728. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1729. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1730. 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.

1731. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1732. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1733. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1734. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1735. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1736. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1737. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 59
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1738. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1739. This cause of action is brought on behalf of the District of Columbia Class (for the purpose of this section, "Class") against all Defendants.

1740. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1741. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1742. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1743. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1744. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1745. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1746. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1747. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the

utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1748. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1749. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1750. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1751. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 60
Strict Products Liability/Design Defect
(Against All Defendants)

1752. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1753. This cause of action is brought on behalf of the District of Columbia Class (for the purpose of this section, "Class") against all Defendants.

1754. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1755. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1756. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1757. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1758. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1759. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1760. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1761. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1762. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1763. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1764. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1765. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1766. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1767. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1768. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1769. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1770. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1771. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

10. Causes of Action Brought on Behalf of the Florida Class

COUNT 61
Breach of Express Warranty
(Fla. Stat. Ann. §672.313)
(Against All Defendants)

1772. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1773. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against all Defendants.

1774. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Fla. Stat. Ann. §672.313 and "sellers" of Ranitidine-Containing Products within the meaning of Fla. Stat. Ann. §672.313.

1775. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Fla. Stat. Ann. §672.313.

1776. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1777. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1778. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1779. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1780. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1781. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1782. Plaintiffs and the Class members gave Defendants reasonable notice of their breaches of express warranty and an opportunity to cure such breaches or, in the alternative, were not required to do so because such an opportunity would be unnecessary and futile given that Defendants are unable to cure the defect in Ranitidine-Containing Products.

1783. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 62
Breach of Implied Warranty
(Fla. Stat. Ann. §672.314)
(Against All Defendants)

1784. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1785. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against all Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Retailer Defendants (for purposes of this section, "Defendants").

1786. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

1787. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Fla. Stat. Ann. §672.314.

1788. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1789. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1790. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1791. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1792. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1793. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 63
Violation of the Florida Deceptive and Unfair Trade Practices Act
(Fla. Stat. Ann. §501.201, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1794. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1795. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1796. The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. Ann. §501.204(1).

1797. In construing the provisions of the FDUTPA, "due consideration and great weight shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to s. 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. s. 45(a)(1) as of July 1, 2017." Fla. Stat. Ann. §501.204(2).

1798. Plaintiffs and Class members are "[c]onsumer[s]" and "[i]nterested part[ies] or person[s]" as defined by the FDUTPA. *See* Fla. Stat. Ann. §501.203(6)-(7).

1799. Defendants engaged in "[t]rade or commerce" as defined by the FDUTPA. *See* Fla. Stat. Ann. §501.203(8).

1800. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the FDUTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1801. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the FDUTPA.

1802. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1803. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1804. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1805. Plaintiffs and the Class members were aggrieved by Defendants' violations of FDUTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have

purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1806. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1807. As a result of Defendants' violations of the FDUTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the FDUTPA.

COUNT 64
Strict Products Liability/Failure to Warn
(Against All Defendants)

1808. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1809. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against all Defendants.

1810. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1811. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1812. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1813. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1814. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1815. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including

Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1816. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1817. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1818. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1819. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1820. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1821. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1822. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1823. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1824. 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.

1825. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1826. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1827. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1828. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1829. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1830. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1831. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 65
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1832. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1833. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against all Defendants.

1834. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1835. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1836. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1837. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1838. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1839. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1840. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1841. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1842. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1843. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1844. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1845. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 66
Strict Products Liability/Design Defect
(Against All Defendants)

1846. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1847. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against all Defendants.

1848. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1849. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1850. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1851. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1852. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1853. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1854. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1855. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1856. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1857. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1858. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1859. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1860. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1861. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1862. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1863. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1864. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1865. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 67
Medical Monitoring
(Against All Defendants)

1866. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1867. This cause of action is brought on behalf of the Florida Class (for the purpose of this section, "Class") against all Defendants.

1868. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

1869. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning,

sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

1870. Defendants breached these duties by, *inter alia,* failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

1871. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA

when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

1872. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

1873. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

1874. Plaintiffs and members of the Class 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.

1875. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

1876. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

1877. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1878. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

1879. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

1880. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1881. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

1882. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1883. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

11. Causes of Action Brought on Behalf of the Georgia Class

COUNT 68
Breach of Express Warranty
(Ga. Code Ann. §11-2-313)
(Against All Defendants)

1884. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1885. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against all Defendants.

1886. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ga. Code Ann. §11-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Ga. Code Ann. §11-2-313.

1887. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ga. Code Ann. §11-2-313.

1888. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as

alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

1889. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

1890. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

1891. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic

properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

1892. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

1893. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

1894. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 69
Breach of Implied Warranty
(Ga. Code Ann. §11-2-314)
(Against All Defendants)

1895. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1896. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against all Defendants.

1897. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiff and members of the Class and were in the business of selling such products.

1898. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ga. Code Ann. §11-2-314.

1899. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

1900. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

1901. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1902. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

1903. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1904. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 70
Violation of the Georgia Fair Business Practices Act
(Ga. Code Ann. §10-1-390, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1905. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1906. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1907. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ga. Code Ann. §10-1-392(a)(24).

1908. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Ga. Code Ann. §10-1-392(a)(6).

1909. Defendants were and are engaged in "[t]rade" and "commerce" within the meaning of Ga. Code Ann. §10-1-392(a)(28).

1910. The Georgia Fair Business Practices Act ("Georgia FBPA") prohibits "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce." Ga. Code Ann. §10-1-393(a).

1911. The Georgia FBPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Ga. Code Ann. §10-1-393(b)(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade or that goods are of a particular style or model, if they are of another" (Ga. Code Ann. §10-1-393(b)(7)); and

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Ga. Code Ann. §10-1-393(b)(9)).

1912. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Georgia FBPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1913. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Georgia FBPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1914. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1915. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1916. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1917. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1918. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Georgia FBPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1919. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Georgia FBPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1920. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1921. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Ga. Code Ann. §10-1-399(b) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

1922. As a result of Defendants' violations of the Georgia FBPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Georgia FBPA.

COUNT 71
Violation of the Georgia Uniform Deceptive Trade Practices Act
(Ga. Code Ann. §10-1-370, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

1923. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1924. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

1925. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ga. Code Ann. §10-1-371(5).

1926. The Georgia Uniform Deceptive Trade Practices Act ("Georgia UDTPA") prohibits "deceptive trade practices . . . in the course of [a] business, vocation, or occupation." Ga. Code Ann. §10-1-372(a).

1927. The Georgia UDTPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Ga. Code Ann. §10-1-372(a)(5));

(b) "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade or that goods are of a particular style or model, if they are of another" (Ga. Code Ann. §10-1-372(a)(7));

(c) "[a]dvertis[ing] goods or services with intent not to sell them as advertised" (Ga. Code Ann. §10-1-372(a)(9)); and

(d) "[e]ngag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding" (Ga. Code Ann. §10-1-372(a)(12)).

1928. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Georgia UDTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

1929. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Georgia UDTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1930. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1931. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class

members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

1932. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1933. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

1934. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Georgia UDTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

1935. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Georgia UDTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used

for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1936. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

1937. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public.

1938. As a result of Defendants' violations of the Georgia UDTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding costs, attorneys' fees, and any other just and proper relief available under the Georgia UDTPA.

COUNT 72
Strict Products Liability/Failure to Warn
(Against All Defendants)

1939. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1940. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against all Defendants.

1941. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

1942. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

1943. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

1944. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

1945. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

1946. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

1947. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

1948. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

1949. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

1950. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

1951. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

1952. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

1953. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

1954. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

1955. 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.

1956. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

1957. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

1958. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

1959. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

1960. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1961. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1962. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 73
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

1963. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1964. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against all Defendants.

1965. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

1966. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

1967. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1968. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

1969. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

1970. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

1971. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

1972. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow CGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

1973. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

1974. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1975. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1976. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 74
Strict Products Liability/Design Defect
(Against All Defendants)

1977. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1978. This cause of action is brought on behalf of the Georgia Class (for the purpose of this section, "Class") against all Defendants.

1979. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

1980. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

1981. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products,

including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

1982. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

1983. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

1984. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

1985. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

1986. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

1987. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

1988. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

1989. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

1990. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

1991. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

1992. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid

(Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

1993. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

1994. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

1995. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

1996. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

12. Causes of Action Brought on Behalf of the Hawaii Class

COUNT 75
Breach of Express Warranty
(Haw. Rev. Stat. Ann. §490:2-313)
(Against All Defendants)

1997. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

1998. This cause of action is brought on behalf of the Hawaii Class (for the purpose of this section, "Class") against all Defendants.

1999. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Haw. Rev. Stat. Ann. §490:2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Haw. Rev. Stat. Ann. §490:2-313.

2000. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Haw. Rev. Stat. Ann. §490:2-313.

2001. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2002. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2003. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2004. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2005. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2006. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2007. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 76
Breach of Implied Warranty
(Haw. Rev. Stat. Ann. §490:2-314)
(Against All Defendants)

2008. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2009. This cause of action is brought on behalf of the Hawaii Class (for the purpose of this section, "Class") against all Defendants.

2010. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2011. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Haw. Rev. Stat. Ann. §490:2-314.

2012. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2013. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2014. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2015. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2016. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2017. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 77
Violation of Hawaii Consumer Protection Law
(Haw. Rev. Stat. Ann. §480, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2018. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2019. This cause of action is brought on behalf of the Hawaii Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2020. Defendants, Plaintiffs, and the Class members are "persons" within the meaning of Haw. Rev. Stat. Ann. §480-1.

2021. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Haw. Rev. Stat. Ann. §480-1.

2022. The Hawaii consumer protection law ("Hawaii Act") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Haw. Rev. Stat. Ann. §480-2(a).

2023. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Hawaii Act by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2024. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Hawaii Act.

2025. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2026. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class

members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2027. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2028. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2029. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Hawaii Act in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2030. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Hawaii Act because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended

purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2031. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2032. Pursuant to Haw. Rev. Stat. Ann. §480-13, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Hawaii Act. Further, under Haw. Rev. Stat. Ann. §480-13.5, the Class members seek an additional award against Defendants of up to $10,000 for each Class member who qualifies as a Hawaiian elder under the Hawaii Act. Defendants knew or should have known that their conduct was directed to one or more Class members who are elders. Defendants' conduct caused one or more of these elders to suffer a substantial loss of property set aside for retirement or for personal or family care and maintenance, or assets essential to the health or welfare of the elder. One or more Class members who are elders are substantially more vulnerable to Defendants' conduct because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and each of them suffered substantial physical, emotional, or economic damage resulting from Defendants' conduct.

COUNT 78
Strict Products Liability/Failure to Warn
(Against All Defendants)

2033. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2034. This cause of action is brought on behalf of the Hawaii Class (for the purpose of this section, "Class") against all Defendants.

2035. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2036. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2037. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2038. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2039. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2040. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2041. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2042. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2043. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2044. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2045. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2046. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2047. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2048. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2049. 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.

2050. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2051. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2052. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2053. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2054. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2055. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2056. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 79
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

2057. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2058. This cause of action is brought on behalf of the Hawaii Class (for the purpose of this section, "Class") against all Defendants.

2059. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2060. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2061. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2062. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2063. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2064. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2065. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2066. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2067. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2068. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2069. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2070. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 80
Strict Products Liability/Design Defect
(Against All Defendants)

2071. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2072. This cause of action is brought on behalf of the Hawaii Class (for the purpose of this section, "Class") against all Defendants.

2073. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2074. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2075. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2076. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2077. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2078. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2079. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2080. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2081. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2082. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2083. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2084. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2085. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2086. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2087. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2088. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2089. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2090. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

13. Causes of Action Brought on Behalf of the Idaho Class

COUNT 81
Breach of Express Warranty
(Idaho Code Ann. §28-2-313)
(Against All Defendants)

2091. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2092. This cause of action is brought on behalf of the Idaho Class (for the purpose of this section, "Class") against all Defendants.

2093. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Idaho Code Ann. §28-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Idaho Code Ann. §28-2-313

2094. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Idaho Code Ann. §28-2-313.

2095. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2096. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2097. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2098. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2099. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2100. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2101. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 82
Breach of Implied Warranty
(Idaho Code Ann. §28-2-314)
(Against All Defendants)

2102. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2103. This cause of action is brought on behalf of the Idaho Class (for the purpose of this section, "Class") against all Defendants.

2104. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2105. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Idaho Code Ann. §28-2-314.

2106. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2107. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2108. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2109. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2110. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2111. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 83
Violation of the Idaho Consumer Protection Act
(Idaho Code Ann. §48-601, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2112. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2113. This cause of action is brought on behalf of the Idaho Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2114. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Idaho Code Ann. §48-602(1).

2115. The Ranitidine-Containing Products are "[g]oods" within the meaning of Idaho Code Ann. §48-602(6).

2116. Defendants were and are engaged in "[t]rade" and "commerce" within the meaning of Idaho Code Ann. §48-602(2).

2117. The Idaho Consumer Protection Act ("Idaho CPA") prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Idaho Code Ann. §48-603.

2118. The Idaho CPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Idaho Code Ann. §48-603(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Idaho Code Ann. §48-603(7));

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Idaho Code Ann. §48-603(9)); and

(d) "[e]ngaging in any act or practice which is otherwise misleading, false, or deceptive to the consumer" (Idaho Code Ann. §48-603(17)).

2119. Idaho law also prohibits "[a]ny unconscionable method, act or practice in the conduct of any trade or commerce." Idaho Code Ann. §48-603C(1).

2120. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Idaho CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2121. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Idaho CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

2122. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2123. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class

members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2124. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2125. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2126. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Idaho CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2127. Plaintiffs and Class members were aggrieved by Defendants' violations of the Idaho CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended

purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2128. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2129. As a result of Defendants' violations of the Idaho CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Idaho CPA.

COUNT 84
Strict Products Liability/Failure to Warn
(Against All Defendants)

2130. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2131. This cause of action is brought on behalf of the Idaho Class (for the purpose of this section, "Class") against all Defendants.

2132. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they

do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2133. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2134. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2135. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2136. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2137. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2138. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2139. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2140. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2141. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used

as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2142. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2143. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2144. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2145. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2146. 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.

2147. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2148. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2149. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2150. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2151. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2152. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2153. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 85
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

2154. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2155. This cause of action is brought on behalf of the Idaho Class (for the purpose of this section, "Class") against all Defendants.

2156. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2157. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2158. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2159. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2160. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2161. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2162. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2163. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the

utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2164. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2165. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2166. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2167. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 86
Strict Products Liability/Design Defect
(Against All Defendants)

2168. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2169. This cause of action is brought on behalf of the Idaho Class (for the purpose of this section, "Class") against all Defendants.

2170. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2171. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2172. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2173. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2174. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2175. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2176. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2177. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2178. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2179. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2180. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2181. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2182. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2183. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2184. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2185. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2186. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2187. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

14. Causes of Action Brought on Behalf of the Illinois Class

COUNT 87
Breach of Express Warranty
(810 Ill. Comp. Stat. Ann. 5/2-313)
(Against All Defendants)

2188. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2189. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against all Defendants.

2190. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of 810 Ill. Comp. Stat. Ann. 5/2-313 and "sellers" of Ranitidine-Containing Products within the meaning of 810 Ill. Comp. Stat. Ann. 5/2-313.

2191. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of 810 Ill. Comp. Stat. Ann. 5/2-313.

2192. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2193. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2194. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2195. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2196. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2197. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2198. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 88
Breach of Implied Warranty
(810 Ill. Comp. Stat. Ann. 5/2-314)
(Against All Defendants)

2199. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2200. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against all Defendants.

2201. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2202. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. 810 Ill. Comp. Stat. Ann. 5/2-314.

2203. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2204. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2205. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2206. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2207. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2208. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 89
Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act
(815 Ill. Comp. Stat. Ann. 505/1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2209. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2210. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2211. Defendants, Plaintiffs, and the Class members are "person[s]" within the meaning of 815 Ill. Comp. Stat. Ann. 505/1(c).

2212. Plaintiffs and the Class members are "consumer[s]" within the meaning of 815 Ill. Comp. Stat. Ann. 505/1(e).

2213. The Ranitidine-Containing Products are "merchandise" within the meaning of 815 Ill. Comp. Stat. Ann. 505/1(b).

2214. Defendants were and are engaged in "trade" and "commerce" within the meaning of 815 Ill. Comp. Stat. Ann. 505/1(f).

2215. The Illinois Consumer Fraud and Deceptive Business Practices Act ("Illinois CFDBPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including, but not limited to, the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' [815 Ill. Comp. Stat. Ann. 510/2], approved August 5, 1965, in the conduct of any trade or commerce." 815 Ill. Comp. Stat. Ann. 505/2.

2216. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Illinois CFDBPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2217. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Illinois CFDBPA.

2218. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2219. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2220. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2221. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2222. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Illinois CFDBPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2223. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Illinois CFDBPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2224. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2225. As a result of Defendants' violations of the Illinois CFDBPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Illinois CFDBPA.

COUNT 90
Violation of the Illinois Uniform Deceptive Trade Practices Act
(815 Ill. Comp. Stat. Ann. 510/1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2226. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2227. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2228. Defendants, Plaintiffs, and the Class members are "person[s]" within the meaning of 815 Ill. Comp. Stat. Ann. 510/1(5).

2229. The Illinois Uniform Deceptive Trade Practices Act ("Illinois UDTPA") prohibits deceptive trade practices "in the course of a business, vocation, or occupation." 815 Ill. Comp. Stat. Ann. 510/2(a).

2230. The Illinois UDTPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (815 Ill. Comp. Stat. Ann. 510/2(a)(5));

(b) "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another" (815 Ill. Comp. Stat. Ann. 510/2(a)(7));

(c) "[a]dvertis[ing] goods or services with intent not to sell them as advertised" (815 Ill. Comp. Stat. Ann. 510/2(a)(9)); and

(d) "[e]ngag[ing] in any other conduct which similarly creates a likelihood of confusion or misunderstanding" (815 Ill. Comp. Stat. Ann. 510/2(a)(12)).

2231. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Illinois UDTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2232. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such

drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Illinois UDTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

2233. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2234. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2235. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2236. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2237. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Illinois UDTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2238. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Illinois UDTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2239. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2240. As a result of Defendants' violations of the Illinois UDTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding costs, attorneys' fees, and any other just and proper relief available under the Illinois UDTPA.

COUNT 91
Strict Products Liability/Failure to Warn
(Against All Defendants)

2241. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2242. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against all Defendants.

2243. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2244. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly

advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2245. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2246. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2247. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2248. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2249. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the

dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2250. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2251. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2252. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2253. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2254. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2255. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2256. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2257. 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.

2258. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known

of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2259. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2260. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2261. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2262. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2263. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage,

subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2264. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 92
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

2265. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2266. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against all Defendants.

2267. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2268. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2269. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2270. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2271. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2272. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2273. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2274. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2275. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2276. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2277. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2278. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 93
Strict Products Liability/Design Defect
(Against All Defendants)

2279. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2280. This cause of action is brought on behalf of the Illinois Class (for the purpose of this section, "Class") against all Defendants.

2281. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2282. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2283. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2284. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2285. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2286. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2287. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2288. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing

Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2289. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2290. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2291. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2292. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2293. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2294. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2295. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2296. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2297. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2298. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

15. Causes of Action Brought on Behalf of the Indiana Class

COUNT 94
Breach of Express Warranty
(Ind. Code Ann. §26-1-2-313)
(Against All Defendants)

2299. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2300. This cause of action is brought on behalf of the Indiana Class (for the purpose of this section, "Class") against all Defendants.

2301. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ind. Code Ann. §26-1-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Ind. Code Ann. §26-1-2-313.

2302. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ind. Code Ann. §26-1-2-313.

2303. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete

warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2304. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2305. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2306. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2307. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2308. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2309. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 95
Breach of Implied Warranty
(Ind. Code Ann. §26-1-2-314)
(Against All Defendants)

2310. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2311. This cause of action is brought on behalf of the Indiana Class (for the purpose of this section, "Class") against all Defendants.

2312. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2313. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ind. Code Ann. §26-1-2-314.

2314. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2315. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2316. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2317. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2318. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2319. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 96
Violation of the Indiana Deceptive Consumer Sales Act
(Ind. Code Ann. §24-5-0.5-3, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2320. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2321. This cause of action is brought on behalf of the Indiana Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2322. Defendants are "[s]upplier[s]" within the meaning of Ind. Code Ann. §24-5-0.5-2(a)(3).

2323. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ind. Code Ann. §24-5-0.5-2(a)(2).

2324. Defendants were and are engaged in "[c]onsumer transaction[s]" within the meaning of Ind. Code Ann. §24-5-0.5-2(a)(1).

2325. The Indiana Deceptive Consumer Sales Act ("Indiana DCSA") prohibits a supplier from committing an "unfair, abusive, or deceptive act, omission, or practice in connection with a consumer transaction." Ind. Code Ann. §24-5-0.5-3(a).

2326. The Indiana DCSA makes unlawful specific acts, including:

(a) "[representing] [t]hat such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits it does not have" (Ind. Code Ann. §24-5-0.5-3(b)(1));

(b) "[representing] [t]hat such subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not and if the

supplier knows or should reasonably know that it is not" (Ind. Code Ann. §24-5-0.5-3(b)(2)); and

(c) "[advertising] [t]hat the consumer will be able to purchase the subject of the consumer transaction as advertised by the supplier, if the supplier does not intend to sell it" (Ind. Code Ann. §24-5-0.5-3(b)(11)).

2327. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Indiana DCSA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2328. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Indiana DCSA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

2329. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2330. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2331. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2332. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2333. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Indiana DCSA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2334. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Indiana DCSA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2335. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2336. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Ind. Code Ann. §24-5-0.5-5(a) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

2337. As a result of Defendants' violations of the Indiana DCSA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Indiana DCSA.

COUNT 97
Products Liability/Failure to Warn
Indiana Product Liability Act
(Against All Defendants)

2338. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2339. This cause of action is brought on behalf of the Indiana Class (for the purpose of this section, "Class") against all Defendants.

2340. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2341. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2342. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2343. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2344. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2345. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2346. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

2347. Before the sale by the Defendants, the Ranitidine-Containing Products, did not comply with applicable codes, standards, regulations, or specifications established, adopted,

promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

2348. Defendants failed to exercise reasonable care under the circumstances in or in providing the warnings or instructions.

2349. Defendants, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer, including healthcare providers.

2350. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2351. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2352. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2353. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2354. Without adequate warnings and/or instructions, the use of a Ranitidine-Containing Products exposed the user or consumer to a risk of physical harm to an extent beyond that contemplated by: (a) the ordinary consumer who purchases the product with the ordinary knowledge about the product's characteristics common to the community of consumers; and (b) sophisticated and learned healthcare providers.

2355. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2356. Plaintiffs and members of Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2357. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2358. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2359. 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.

2360. Additionally, Defendants breached their duty to adequately warn of Ranitidine-Containing Products' risks because they labeled Ranitidine-Containing Products in a false and misleading manner that omitted any mention of the drugs' propensity to expose users to NDMA and failed to suggest or recommend a manner of using Ranitidine-Containing Products so that they are not dangerous to consumers' health when used as labeled and directed, thereby manufacturing, repackaging, offering for sale, delivering, and/or holding misbranded drugs in violation of 21 U.S.C. §§331, 352(a)(1), (j) and Indiana Code §§16-42-1-16(1),(2) & 16-42-3-4(1), (14).

2361. Defendants' duties as set forth in the above-mentioned statutes parallel their state common-law duty to exercise reasonable care in the warning and labeling of Ranitidine-Containing Products.

2362. The Indiana and United States legislatures designed the above-mentioned statutes to bolster consumer protection against dangerous pharmaceutical products and to supplement common-law liability for manufacturers of defectively designed and misbranded drugs.

2363. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in Indiana, are within the specific class of persons that the above-mentioned statutes were designed to protect.

2364. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

2365. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly labeled Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

2366. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2367. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2368. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2369. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2370. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2371. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2372. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 98
Products Liability/Manufacturing Defect
Indiana Product Liability Act
(Against All Defendants)

2373. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2374. This cause of action is brought on behalf of the Indiana Class (for the purpose of this section, "Class") against all Defendants.

2375. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2376. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

2377. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2378. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2379. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2380. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2381. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2382. The use of a Ranitidine-Containing Products exposed the user or consumer to a risk of physical harm to an extent beyond that contemplated by: (a) the ordinary consumer who purchases the product with the ordinary knowledge about the product's characteristics common to the community of consumers; and (b) sophisticated and learned healthcare providers.

2383. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2384. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

2385. Before the sale by the Defendants, the Ranitidine-Containing Products, did not comply with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

2386. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2387. Defendants failed to exercise reasonable care under the circumstances in designing the Ranitidine-Containing Products.

2388. Defendants further breached their duty of reasonable care and manufactured Ranitidine-Containing Products in an unreasonably dangerous condition, in that while representing carcinogenic Ranitidine-Containing Products as safe, Defendants failed to employ manufacturing methods to assure Ranitidine-Containing Products met the quality and purity characteristics they purported to possess, thereby manufacturing, repackaging, offering for sale, selling, delivering, and/or holding adulterated drugs in violation of 21 U.S.C. §§331, 351(a)(2)(B) and Indiana Code §16-42-1-16(1), (2) &16-43-3-3(3)(B).

2389. Defendants' duties as specified in the above-mentioned statutes parallel their common-law duty to exercise reasonable care in manufacturing Ranitidine-Containing Products.

2390. The Indiana and United States legislatures designed the above-mentioned statutes to protect pharmaceutical consumers by bolstering consumer protection against dangerous pharmaceutical products and supplementing common-law liability for manufacturers of adulterated drugs.

2391. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in Indiana, are within the specific class of persons that the above-mentioned statutes were designed to protect.

2392. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

2393. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly manufactured and defective Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

2394. Additionally, Manufacturer Defendants breached their duty to manufacture a safe product by failing to follow cGMPs in the storing, handling, and warehousing of Ranitidine-Containing Products, thereby increasing the risk that the drugs would produce NDMA during storage and/or transport, in that Defendants failed to ensure that Ranitidine-Containing Products were stored, handled, and warehoused under appropriate conditions of temperature, humidity, and light so that their identity, strength, quality, and purity was not adversely affected, in violation of the cGMPs set forth in 21 C.F.R. §211.142(b).

2395. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2396. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2397. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2398. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 99
Products Liability/Design Defect
Indiana Product Liability Act
(Against All Defendants)

2399. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2400. This cause of action is brought on behalf of the Indiana Class (for the purpose of this section, "Class") against all Defendants.

2401. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2402. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing, designing, and labeling Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

2403. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2404. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

2405. Before the sale by the Defendants, the Ranitidine-Containing Products, did not comply with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

2406. Defendants failed to exercise reasonable care under the circumstances in designing the Ranitidine-Containing Products.

2407. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2408. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2409. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2410. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2411. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2412. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2413. Defendants further breached their duty of care and designed a defective product because they labeled Ranitidine-Containing Products in a false and misleading manner that omitted any mention of the drugs' propensity to expose users to NDMA and failed to suggest or recommend a manner of using Ranitidine-Containing Products so that they are not dangerous to consumers' health when used as labeled and directed, thereby manufacturing, repackaging, offering for sale, delivering, and/or holding misbranded drugs in violation of 21 U.S.C. §§331, 352(a)(1), (j) and Indiana Code §§16-42-1-16(1),(2) and -3-4(1), (14).

2414. Defendants' duties as set forth in the above-mentioned statutes parallel their state common-law duty to exercise reasonable care in the designing and labeling of Ranitidine-Containing Products.

2415. The Indiana and United States legislatures designed the above-mentioned statutes to bolster consumer protection against dangerous pharmaceutical products and to supplement common-law liability for manufacturers of defectively designed and misbranded drugs.

2416. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in Indiana, are within the specific class of persons that the above-mentioned statutes were designed to protect.

2417. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

2418. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly labeled and designed Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

2419. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2420. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2421. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to

Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2422. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2423. The use of Ranitidine-Containing Products exposed the user or consumer to a risk of physical harm to an extent beyond that contemplated by: (a) the ordinary consumer who purchases the product with the ordinary knowledge about the product's characteristics common to the community of consumers; and (b) sophisticated and learned healthcare providers.

2424. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2425. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2426. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2427. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2428. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2429. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

16. Causes of Action Brought on Behalf of the Iowa Class

COUNT 100
Breach of Express Warranty
(Iowa Code Ann. §554.2313)
(Against All Defendants)

2430. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2431. This cause of action is brought on behalf of the Iowa Class (for the purpose of this section, "Class") against all Defendants.

2432. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Iowa Code Ann. §554.2313 and "sellers" of Ranitidine-Containing Products within the meaning of Iowa Code Ann. §554.2313.

2433. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Iowa Code Ann. §554.2313.

2434. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2435. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2436. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2437. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who

were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

2438. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2439. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings

and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2440. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2441. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 101
Breach of Implied Warranty
(Iowa Code Ann. §554.2314)
(Against All Defendants)

2442. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2443. This cause of action is brought on behalf of the Iowa Class (for the purpose of this section, "Class") against all Defendants.

2444. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2445. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Iowa Code Ann. §554.2314 (2016).

2446. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform

to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2447. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2448. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2449. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2450. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2451. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 102
Violation of the Iowa Private Right of Action for Consumer Frauds Act
(Iowa Code Ann. §714H.1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2452. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2453. This cause of action is brought on behalf of the Iowa Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2454. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Iowa Code Ann. §714H.2(7).

2455. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Iowa Code Ann. §714H.2(3).

2456. The Iowa Private Right of Action for Consumer Frauds Act ("Iowa PRACFA") prohibits any "practice or act the person knows or reasonably should know is an unfair practice, deception, fraud, false pretense, or false promise, or the misrepresentation, concealment, suppression, or omission of a material fact, with the intent that others rely upon the unfair practice, deception, fraud, false pretense, false promise, misrepresentation, concealment, suppression, or omission in connection with the advertisement, sale, or lease of consumer merchandise." Iowa Code Ann. §714H.3(1).

2457. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Iowa PRACFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit

to be used for their intended purpose, as detailed above. Defendants did so with willful and wanton disregard for the rights and safety of others.

2458. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Iowa PRACFA.

2459. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2460. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2461. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2462. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had

concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2463. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Iowa PRACFA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2464. Plaintiffs and Class members suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' concealment, misrepresentations, and/or failure to disclose material information.

2465. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2466. As a result of Defendants' violations of the Iowa PRACFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Iowa PRACFA.

COUNT 103
Strict Products Liability/Failure to Warn
(Against All Defendants)

2467. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2468. This cause of action is brought on behalf of the Iowa Class (for the purpose of this section, "Class") against all Defendants.

2469. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2470. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2471. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2472. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2473. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2474. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2475. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2476. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products.

Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2477. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous and not reasonably safe.

2478. The risks of NDMA formation and carcinogenic characteristics of the Ranitidine-Containing Products was not obvious to, or generally known by, foreseeable product users, *i.e.*, end users and healthcare providers.

2479. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2480. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2481. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2482. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2483. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each

Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2484. 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.

2485. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2486. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2487. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2488. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2489. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2490. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2491. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 104
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

2492. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2493. This cause of action is brought on behalf of the Iowa Class (for the purpose of this section, "Class") against all Defendants.

2494. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2495. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2496. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2497. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2498. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2499. The Ranitidine-Containing Products contained a manufacturing defect or defects that departed from the intended design at the time they left the defendant's control.

2500. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2501. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2502. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2503. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2504. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2505. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2506. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 105
Strict Products Liability/Design Defect
(against All Defendants

2507. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2508. This cause of action is brought on behalf of the Iowa Class (for the purpose of this section, "Class") against all Defendants.

2509. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At

all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2510. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2511. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2512. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2513. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2514. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2515. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2516. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2517. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2518. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2519. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2520. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2521. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-

Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2522. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2523. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2524. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2525. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2526. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

17. Causes of Action Brought on Behalf of the Kansas Class

COUNT 106
Breach of Express Warranty
(Kan. Stat. Ann. §84-2-313)
(Against All Defendants)

2527. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2528. This cause of action is brought on behalf of the Kansas Class (for the purpose of this section, "Class") against all Defendants.

2529. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Kan. Stat. Ann. §84-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Kan. Stat. Ann. §84-2-313.

2530. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Kan. Stat. Ann. §84-2-313.

2531. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2532. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2533. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2534. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2535. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2536. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2537. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 107
Breach of Implied Warranty
(Kan. Stat. Ann. §84-2-314)
(Against All Defendants)

2538. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2539. This cause of action is brought on behalf of the Kansas Class (for the purpose of this section, "Class") against all Defendants.

2540. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2541. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Kan. Stat. Ann. §84-2-314.

2542. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2543. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2544. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2545. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2546. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2547. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 108
Violation of the Kansas Consumer Protection Act
(Kan. Stat. Ann. §50-623, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2548. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2549. This cause of action is brought on behalf of the Kansas Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2550. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Kan. Stat. Ann. §50-624(i).

2551. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Kan. Stat. Ann. §50-624(b).

2552. The Kansas Consumer Protection Act ("Kansas CPA") prohibits deceptive or unconscionable acts or practices in connection with a consumer transactions. Kan. Stat. Ann. §§50-626 and 50-627.

2553. The Kansas CPA makes unlawful specific acts, including:

(a) "[r]epresentations made knowingly or with reason to know that . . . [p]roperty or services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have" (Kan. Stat. Ann. §50-626(b)(1)(A));

(b) "[r]epresentations made knowingly or with reason to know that . . . property or services are of particular standard, quality, grade, style or model, if they are of another which differs materially from the representation" (Kan. Stat. Ann. §50-626(b)(1)(D));

(c) "[t]he willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact" (Kan. Stat. Ann. §50-626(b)(2));

(d) "[t]he willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact." (Kan. Stat. Ann. §50-626(b)(3)); and

(e) "[o]ffering property or services without intent to sell them" (Kan. Stat. Ann. §50-626(b)(5)).

2554. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Kansas CPA by knowingly and intentionally misrepresenting, omitting,

concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2555. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Kansas CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) using exaggeration and/or failing to state the material facts concerning the Ranitidine-Containing Products in a manner that tended to deceive;

(e) acting in a manner that resulted in a gross disparity between the true value of the Ranitidine-Containing Products and the price paid; and

(f) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

2556. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2557. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were

likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2558. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2559. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2560. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Kansas CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2561. Plaintiffs and Class members suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' concealment, misrepresentations, and/or failure to disclose material information.

2562. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2563. As a result of Defendants' violations of the Kansas CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Kansas CPA.

COUNT 109
Products Liability/Failure to Warn
(Against All Defendants)

2564. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2565. This cause of action is brought on behalf of the Kansas Class (for the purpose of this section, "Class") against all Defendants.

2566. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2567. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly

advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2568. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2569. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2570. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2571. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2572. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the

dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2573. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2574. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2575. A reasonably prudent manufacturer, distributor, or seller could and would have taken additional precautions.

2576. These warnings which the Defendants failed to provide, were not warnings: (a) protecting against or instructing with regard to those safeguards, precautions, and actions which a reasonable user or consumer of the product, with the training, experience, education, and any special knowledge the user or consumer did, should or was required to possess, could and should have taken for such user or consumer or others, under all the facts and circumstances; (b) extending to situations where the safeguards, precautions, and actions would or should have been taken by a reasonable user or consumer of the product similarly situated exercising reasonable care, caution,

and procedure; or (c) protecting against or instructing with regard to dangers, hazards, or risks which are patent, open, or obvious and which should have been realized by a reasonable user or consumer of the product.

2577. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2578. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2579. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2580. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2581. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2582. 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.

2583. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2584. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2585. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products,

Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2586. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2587. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2588. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2589. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 110
Products Liability/Manufacturing Defect
(Against All Defendants)

2590. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2591. This cause of action is brought on behalf of the Kansas Class (for the purpose of this section, "Class") against all Defendants.

2592. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2593. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

2594. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2595. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2596. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2597. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2598. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2599. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2600. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2601. A reasonably prudent manufacturer, distributor, or seller exercising reasonable and due care could and would have taken additional precautions.

2602. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2603. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2604. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2605. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 111
Products Liability/Design Defect
(Against All Defendants)

2606. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2607. This cause of action is brought on behalf of the Kansas Class (for the purpose of this section, "Class") against all Defendants.

2608. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2609. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing, designing, and labeling Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

2610. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2611. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2612. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2613. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous

to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2614. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2615. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2616. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2617. A reasonably prudent manufacturer, distributor, or seller could and would have taken additional precautions.

2618. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2619. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2620. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2621. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2622. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2623. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2624. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2625. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2626. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2627. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

18. Causes of Action Brought on Behalf of the Kentucky Class

COUNT 112
Breach of Express Warranty
(Ky. Rev. Stat. Ann. §355.2-313)
(Against All Defendants)

2628. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2629. This cause of action is brought on behalf of the Kentucky Class (for the purpose of this section, "Class") against all Defendants.

2630. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ky. Rev. Stat. Ann. §355.2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Ky. Rev. Stat. Ann. §355.2-313.

2631. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ky. Rev. Stat. Ann. §355.2-313.

2632. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete

warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2633. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2634. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2635. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2636. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2637. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2638. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 113
Breach of Implied Warranty
(Ky. Rev. Stat. Ann. §355.2-314)
(Against All Defendants)

2639. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2640. This cause of action is brought on behalf of the Kentucky Class (for the purpose of this section, "Class") against all Defendants.

2641. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiff members of and the Class and were in the business of selling such products.

2642. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ky. Rev. Stat. Ann. §355.2-314.

2643. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2644. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2645. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2646. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2647. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2648. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 114
Violation of the Kentucky Consumer Protection Act
(Ky. Rev. Stat. Ann. §367.110, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2649. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2650. This cause of action is brought on behalf of the Kentucky Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2651. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ky. Rev. Stat. Ann. §367.110(1).

2652. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Ky. Rev. Stat. Ann. §367.110(2).

2653. The Kentucky Consumer Protection Act ("Kentucky CPA") prohibits "[u]nfair, [unconscionable], false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." Ky. Rev. Stat. Ann. §367.170(1)-(2).

2654. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Kentucky CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2655. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such

drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Kentucky CPA.

2656. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2657. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2658. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2659. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2660. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Kentucky CPA in the course of their business. Specifically,

Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2661. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Kentucky CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2662. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2663. As a result of Defendants' violations of the Kentucky CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Kentucky CPA.

COUNT 115
Strict Products Liability/Failure to Warn
(Against All Defendants)

2664. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2665. This cause of action is brought on behalf of the Kentucky Class (for the purpose of this section, "Class") against all Defendants.

2666. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2667. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2668. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2669. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2670. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2671. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2672. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

2673. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2674. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2675. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2676. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2677. Without adequate warnings and/or instructions, an ordinary manufacturer, being fully aware of the risks, would not have placed Ranitidine-Containing Products on the market.

2678. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2679. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2680. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2681. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2682. 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.

2683. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2684. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2685. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2686. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2687. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2688. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2689. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 116
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

2690. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2691. This cause of action is brought on behalf of the Kentucky Class (for the purpose of this section, "Class") against all Defendants.

2692. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2693. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2694. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2695. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2696. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their

manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2697. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2698. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2699. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

2700. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2701. An ordinary manufacturer, being fully aware of the risks, would not have placed Ranitidine-Containing Products on the market.

2702. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2703. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2704. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2705. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 117
Strict Products Liability/Design Defect
(Against All Defendants)

2706. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2707. This cause of action is brought on behalf of the Kentucky Class (for the purpose of this section, "Class") against all Defendants.

2708. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2709. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2710. The design, methods of manufacture, and testing of Defendants' Ranitidine-Containing Products failed to conform to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared and the product was manufactured.

2711. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2712. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2713. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2714. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2715. An ordinary manufacturer, being fully aware of the risks, would not have placed Ranitidine-Containing Products on the market.

2716. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2717. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled,

distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2718. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2719. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2720. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2721. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2722. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2723. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2724. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2725. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2726. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2727. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

19. Causes of Action Brought on Behalf of the Louisiana Class

COUNT 118
Breach of Express Warranty
(La. Rev. Stat. §51:2763)
(Against All Defendants)

2728. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2729. This cause of action is brought on behalf of the Louisiana Class (for the purpose of this section, "Class") against all Defendants.

2730. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of La. Rev. Stat. §51:2763 and "sellers" of Ranitidine-Containing Products within the meaning of La. Rev. Stat. §51:2763.

2731. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of La. Rev. Stat. §51:2763.

2732. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2733. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2734. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2735. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the

Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2736. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2737. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2738. Plaintiffs and the Class members gave Defendants reasonable notice of their breaches of express warranty and an opportunity to cure such breaches or, in the alternative, were not required to do so because such an opportunity would be unnecessary and futile given that Defendants are unable to cure the defect in Ranitidine-Containing Products.

2739. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 119
Breach of Warranty Against Redhibitory Defects
(La. Civ. Code Ann. Art. §2520)
(Against Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Retailer Defendants)

2740. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2741. This cause of action is brought on behalf of the Louisiana Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants, and Retailer Defendants (for purposes of this section, "Defendants").

2742. At all relevant times, Defendants were sellers with respect to Ranitidine-Containing Products which were sold to Plaintiff and the Class and were in the business of selling such products.

2743. Each Ranitidine-Containing Product sold by Defendants comes with a warranty against redhibitory defects. La. Civ. Code Ann. Art. §2520.

2744. Defendants breached their implied warranty of against redhibitory defects because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2745. Defendants' Ranitidine-Containing Products are rendered useless because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2746. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2747. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2748. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of warranty against redhibitory defects. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of warranty against redhibitory defects because, had they been aware of the defective condition of Ranitidine-Containing Products that rendered them useless, or so inconvenient that they would not have purchased such drugs.

2749. As a result of Defendants' breaches of warranty against redhibitory defect, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 120
Violation of the Louisiana Unfair Trade Practices and Consumer Protection Law
(La. Stat. Ann. §51:1401, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2750. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2751. This cause of action is brought on behalf of the Louisiana Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2752. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of La. Stat. Ann. §51:1402(8).

2753. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of La. Stat. Ann. §51:1402(1).

2754. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of La. Stat. Ann. §51:1402(10).

2755. The Louisiana Unfair Trade Practices and Consumer Protection Law ("Louisiana CPL") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." La. Stat. Ann. §51:1405(A).

2756. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Louisiana CPL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2757. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Louisiana CPL.

2758. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2759. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2760. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2761. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

2762. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2763. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Louisiana CPL in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2764. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Louisiana CPL because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2765. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2766. As a result of Defendants' violations of the Louisiana CPL, as alleged herein, Plaintiffs and the Class members seek an order awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Louisiana CPL.

COUNT 121
Products Liability/Failure to Warn
Louisiana Product Liability Act
(Against All Defendants)

2767. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2768. This cause of action is brought on behalf of the Louisiana Class (for the purpose of this section, "Class") against all Defendants.

2769. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2770. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2771. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2772. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2773. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2774. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2775. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2776. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2777. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2778. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2779. At and after the time the product left Defendants' control, the product possessed a characteristic that may cause cancer. Defendants failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

2780. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2781. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2782. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2783. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2784. 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.

2785. Defendants failed to use reasonable care to provide adequate warnings to the users and handlers of the Ranitidine-Containing Products. Defendants had knowledge of the dangerous characteristics of the Ranitidine-Containing Products and/or would have acquired knowledge had they acted as a reasonably prudent manufacturer.

2786. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2787. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2788. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2789. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2790. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2791. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2792. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 122
Products Liability/Manufacturing Defect
Louisiana Product Liability Act
(Against All Defendants)

2793. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2794. This cause of action is brought on behalf of the Louisiana Class (for the purpose of this section, "Class") against all Defendants.

2795. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2796. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2797. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2798. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2799. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2800. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2801. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2802. The Ranitidine-Containing Products deviated in a material way from the Defendants' specifications or performance standards for the product or from otherwise identical products manufactured by the same Defendant.

2803. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and

treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2804. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2805. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2806. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2807. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of

developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 123
Products Liability/Design Defect
Louisiana Product Liability Act
(Against All Defendants)

2808. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2809. This cause of action is brought on behalf of the Louisiana Class (for the purpose of this section, "Class") against all Defendants.

2810. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2811. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2812. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by

Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2813. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2814. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2815. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2816. The likelihood that the Ranitidine-Containing Products design would cause Plaintiffs and members of the Class damage, and the gravity of that damage, outweighed the burden on the manufacturer of adopting such alternative design, and the adverse effect, if any, of such alternative design on the utility of the product. Defendants did not use reasonable care to provide an adequate warning to users and handlers of the product.

2817. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2818. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2819. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2820. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2821. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2822. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2823. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2824. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants'

Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2825. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2826. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2827. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2828. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

20. Causes of Action Brought on Behalf of the Maine Class

COUNT 124
Breach of Express Warranty
(Me. Rev. Stat. Ann. tit. 11, §2-313)
(Against All Defendants)

2829. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2830. This cause of action is brought on behalf of the Maine Class (for the purpose of this section, "Class") against all Defendants.

2831. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Me. Rev. Stat. Ann. tit. 11, §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Me. Rev. Stat. Ann. tit. 11, §2-313.

2832. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Me. Rev. Stat. Ann. tit. 11, §2-313.

2833. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2834. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2835. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the

buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2836. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2837. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2838. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2839. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 125
Breach of Implied Warranty
(Me. Rev. Stat. Ann. tit. 11, §2-314)
(Against All Defendants)

2840. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2841. This cause of action is brought on behalf of the Maine Class (for the purpose of this section, "Class") against all Defendants.

2842. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2843. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Me. Rev. Stat. Ann. tit. 11, §2-314.

2844. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2845. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2846. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2847. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2848. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2849. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 126
Violation of the Maine Unfair Trade Practices Act
(Me. Rev. Stat. Ann. tit. 5, §205-a, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2850. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2851. This cause of action is brought on behalf of the Maine Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2852. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Me. Rev. Stat. Ann. tit. 5, §206(2).

2853. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Me. Rev. Stat. Ann. tit. 5, §206(3).

2854. The Maine Unfair Trade Practices Act ("Maine UTPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Me. Rev. Stat. Ann. tit. 5, §207.

2855. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Maine UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2856. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Maine UTPA.

2857. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2858. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were

likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2859. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2860. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

2861. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2862. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Maine UTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2863. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Maine UTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2864. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2865. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Me. Rev. Stat. Ann. tit. 5, §213(1-A) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

2866. As a result of Defendants' violations of the Maine UTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Maine UTPA.

COUNT 127
Strict Products Liability/Failure to Warn
(Me. Rev. Stat. Ann. tit. 14, §221)
(Against All Defendants)

2867. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2868. This cause of action is brought on behalf of the Maine Class (for the purpose of this section, "Class") against all Defendants.

2869. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2870. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2871. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2872. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2873. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2874. The danger was foreseeable based on scientific, technological, and other information available.

2875. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2876. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their

drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2877. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2878. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2879. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2880. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2881. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2882. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2883. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2884. 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.

2885. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2886. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2887. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2888. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2889. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2890. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2891. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 128
Strict Products Liability/Manufacturing Defect
(Me. Rev. Stat. Ann. tit. 14, §221)
(Against All Defendants)

2892. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2893. This cause of action is brought on behalf of the Maine Class (for the purpose of this section, "Class") against all Defendants.

2894. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2895. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2896. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2897. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2898. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their

manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2899. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2900. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2901. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2902. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

2903. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2904. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2905. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 129
Strict Products Liability/Design Defect
(Me. Rev. Stat. Ann. tit. 14, §221)
(Against All Defendants)

2906. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2907. This cause of action is brought on behalf of the Maine Class (for the purpose of this section, "Class") against all Defendants.

2908. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including

Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

2909. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

2910. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

2911. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2912. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous

to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

2913. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

2914. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

2915. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

2916. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

2917. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

2918. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

2919. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

2920. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an

ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

2921. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

2922. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

2923. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2924. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2925. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of

developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

21. Causes of Action Brought on Behalf of the Maryland Class

COUNT 130
Breach of Express Warranty
(Md. Code Ann., Com. Law §2-313)
(Against All Defendants)

2926. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2927. This cause of action is brought on behalf of the Maryland Class (for the purpose of this section, "Class") against all Defendants.

2928. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Md. Code Ann., Com. Law §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Md., Code Ann. Com. Law §2-313.

2929. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Md. Code Ann., Com. Law §2-313.

2930. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

2931. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

2932. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

2933. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

2934. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably

discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

2935. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

2936. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 131
Breach of Implied Warranty
(Md. Code Ann., Com. Law §2-314)
(Against All Defendants)

2937. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2938. This cause of action is brought on behalf of the Maryland Class (for the purpose of this section, "Class") against all Defendants.

2939. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

2940. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Md. Code Ann., Com. Law §2-314.

2941. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not

possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

2942. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

2943. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

2944. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

2945. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

2946. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 132
Violation of the Maryland Consumer Protection Act
(Md. Code Ann., Com. Law §13-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

2947. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2948. This cause of action is brought on behalf of the Maryland Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

2949. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Md. Code Ann., Com. Law §13-101(h).

2950. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Md. Code Ann., Com. Law §13-101(c)(1).

2951. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Md. Code Ann., Com. Law §13-101(f).

2952. The Maryland Consumer Protection Act ("Maryland CPA") prohibits "[u]nfair, abusive, or deceptive trade practices." Md. Code Ann., Com. Law §13-301.

2953. The Maryland CPA makes unlawful specific acts, including:

(a) "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers" (Md. Code Ann., Com. Law §13-301(1));

(b) "[r]epresent[ing] that . . . [c]onsumer goods, consumer realty, or consumer services have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have" (Md. Code Ann., Com. Law §13-301(2)(i));

(c) "[r]epresent[ing] that . . . [c]onsumer goods, consumer realty, or consumer services are of a particular standard, quality, grade, style, or model which they are not" (Md. Code Ann., Com. Law §13-301(2)(iv));

(d) "[f]ailure to state a material fact if the failure deceives or tends to deceive" (Md. Code Ann., Com. Law §13-301(3));

(e) "[a]dvertis[ing] or offer[ing] of consumer goods, consumer realty, or consumer services . . . [w]ithout intent to sell, lease, or rent them as advertised or offered" (Md. Code Ann., Com. Law §13-301(5)(i)); and

(f) "[d]eception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with . . . [t]he promotion or sale of any consumer goods" (Md. Code Ann., Com. Law §13-301(9)(i)).

2954. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Maryland CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

2955. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Maryland CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) failing to disclose that the Ranitidine-Containing Products are defective and inherently dangerous in the course of the sale of the Ranitidine-Containing Products; and

(e) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

2956. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

2957. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

2958. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

2959. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

2960. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

2961. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Maryland CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

2962. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Maryland CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

2963. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

2964. As a result of Defendants' violations of the Maryland CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Maryland CPA.

COUNT 133
Strict Products Liability/Failure to Warn
(Against All Defendants)

2965. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2966. This cause of action is brought on behalf of the Maryland Class (for the purpose of this section, "Class") against all Defendants.

2967. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

2968. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

2969. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

2970. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

2971. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

2972. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

2973. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

2974. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

2975. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

2976. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

2977. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

2978. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

2979. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

2980. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

2981. 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.

2982. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

2983. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

2984. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

2985. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

2986. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

2987. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

2988. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 134
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

2989. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

2990. This cause of action is brought on behalf of the Maryland Class (for the purpose of this section, "Class") against all Defendants.

2991. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

2992. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

2993. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

2994. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

2995. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

2996. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

2997. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

2998. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

2999. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3000. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3001. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3002. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 135
Strict Products Liability/Design Defect
(Against All Defendants)

3003. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3004. This cause of action is brought on behalf of the Maryland Class (for the purpose of this section, "Class") against all Defendants.

3005. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3006. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3007. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3008. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3009. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3010. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3011. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3012. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3013. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3014. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3015. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3016. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3017. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3018. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3019. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3020. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3021. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3022. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

22. Causes of Action Brought on Behalf of the Massachusetts Class

COUNT 136
Breach of Express Warranty
(Mass. Gen. Laws Ann. Ch. 106 §2-313)
(Against All Defendants)

3023. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3024. This cause of action is brought on behalf of the Massachusetts Class (for the purpose of this section, "Class") against all Defendants.

3025. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Mass. Gen. Laws Ann. Ch. 106 §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Mass. Gen. Laws Ann. Ch. 106 §2-313.

3026. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Mass. Gen. Laws Ann. Ch. 106 §2-313.

3027. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3028. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3029. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3030. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3031. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3032. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3033. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 137
Breach of Implied Warranty
(Mass. Gen. Laws Ann. Ch. 106 §2-314)
(Against All Defendants)

3034. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3035. This cause of action is brought on behalf of the Massachusetts Class (for the purpose of this section, "Class") against all Defendants.

3036. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3037. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Mass. Gen. Laws Ann. Ch. 106 §2-314.

3038. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3039. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3040. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3041. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3042. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3043. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 138
Violation of the Deceptive Acts or Practices Prohibited by Massachusetts Law
(Mass. Gen. Laws Ann. ch. 93a, §1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3044. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3045. This cause of action is brought on behalf of the Massachusetts Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3046. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Mass. Gen. Laws Ann. ch. 93A, §1(a).

3047. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Mass. Gen. Laws Ann. ch. 93A, §1(b).

3048. The Massachusetts consumer protection law ("Massachusetts Act") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws Ann. ch. 93A, §2(a).

3049. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Massachusetts Act by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3050. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Massachusetts Act.

3051. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3052. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3053. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3054. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3055. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Massachusetts Act in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3056. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Massachusetts Act because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3057. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3058. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Mass. Gen. Laws Ann. ch. 93A, §9(3) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

3059. As a result of Defendants' violations of the Massachusetts Act, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Massachusetts Act.

COUNT 139
Medical Monitoring
(Against All Defendants)

3060. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3061. This cause of action is brought on behalf of the Massachusetts Class (for the purpose of this section, "Class") against all Defendants.

3062. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

3063. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

3064. Defendants breached these duties by, *inter alia*, failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

3065. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

3066. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

3067. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

3068. Plaintiffs and members of the Class 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.

3069. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

3070. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

3071. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3072. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This

diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

3073. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

3074. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3075. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

3076. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3077. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

23. Causes of Action Brought on Behalf of the Michigan Class

COUNT 140
Breach of Express Warranty
(Mich. Comp. Laws Ann. §440.2313)
(Against All Defendants)

3078. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3079. This cause of action is brought on behalf of the Michigan Class (for the purpose of this section, "Class") against all Defendants.

3080. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Mich. Comp. Laws Ann. §440.2313 and "sellers" of Ranitidine-Containing Products within the meaning of Mich. Comp. Laws Ann. §440.2313.

3081. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Mich. Comp. Laws Ann. §440.2313.

3082. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3083. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3084. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3085. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3086. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3087. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3088. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 141
Breach of Implied Warranty
(Mich. Comp. Laws Ann. §440.2314)
(Against All Defendants)

3089. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3090. This cause of action is brought on behalf of the Michigan Class (for the purpose of this section, "Class") against all Defendants.

3091. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3092. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Mich. Comp. Laws Ann. §440.2314.

3093. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3094. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3095. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3096. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3097. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3098. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 142
Violation of the Michigan Consumer Protection Act
(Mich. Comp. Laws Ann. §445.901, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3099. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3100. This cause of action is brought on behalf of the Michigan Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3101. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Mich. Comp. Laws Ann. §445.902(1)(d).

3102. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Mich. Comp. Laws Ann. §445.902(1)(g).

3103. The Michigan Consumer Protection Act ("Michigan CPA") prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce." Mich. Comp. Laws Ann. §445.903(1).

3104. The Michigan CPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Mich. Comp. Laws Ann. §445.903(1)(c));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Mich. Comp. Laws Ann. §445.903(1)(e)); and

(c) "[a]dvertising or representing goods or services with intent not to dispose of those goods or services as advertised or represented" (Mich. Comp. Laws Ann. §445.903(1)(g)).

3105. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Michigan CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3106. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Michigan CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

3107. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3108. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3109. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3110. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3111. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Michigan CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3112. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Michigan CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would

not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3113. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3114. As a result of Defendants' violations of the Michigan CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Michigan CPA.

24. Causes of Action Brought on Behalf of the Minnesota Class

COUNT 143
Breach of Express Warranty
(Minn. Stat. Ann. §336.2-313)
(Against All Defendants)

3115. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3116. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against all Defendants.

3117. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Minn. Stat. Ann. §336.2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Minn. Stat. Ann. §336.2-313.

3118. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Minn. Stat. Ann. §336.2-313.

3119. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for

consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3120. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3121. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3122. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of

Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and

Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3123. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3124. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3125. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 144
Breach of Implied Warranty
(Minn. Stat. Ann. §336.2-314)
(Against All Defendants)

3126. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3127. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against all Defendants.

3128. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3129. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Minn. Stat. Ann. §336.2-314.

3130. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3131. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3132. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3133. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3134. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the

Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3135. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 145
Violation of the Minnesota Prevention of Consumer Fraud Act
(Minn. Stat. Ann. §325F.68, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3136. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3137. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3138. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Minn. Stat. Ann. §325F.68(3).

3139. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Minn. Stat. Ann. §325F.68(2).

3140. The Minnesota Prevention of Consumer Fraud Act ("Minnesota CFA") prohibits "act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged." Minn. Stat. Ann. §325F.69(1). Prohibited practices include: (i)

deceptive practices concerning the quality of goods or services pursuant to Minn. Stat. Ann. §325D.44; (ii) fraud in connection with the sale of any merchandise pursuant to Minn. Stat. Ann. §325F.69; and (iii) misrepresentation of product ingredients or quality pursuant to Minn. Stat. Ann. §325D.13.

3141. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Minnesota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3142. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Minnesota CFA.

3143. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3144. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3145. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3146. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

3147. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3148. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Minnesota CFA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3149. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Minnesota CFA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions,

concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3150. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3151. As a result of Defendants' violations of the Minnesota CFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Minnesota CFA.

COUNT 146
Violation of the Minnesota Uniform Deceptive Trade Practices Act
(Minn. Stat. Ann. §325D.43, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3152. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3153. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3154. The Minnesota Uniform Deceptive Trade Practices Act ("Minnesota UDTPA") prohibits deceptive trade practices "in the course of a business, vocation, or occupation." Minn. Stat. Ann. §325D.44, Subd. 1.

3155. The Minnesota UDTPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Minn. Stat. Ann. §325D.44, Subd. 1(5));

(b) "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Minn. Stat. Ann. §325D.44, Subd. 1(7));

(c) "[a]dvertis[ing] goods or services with intent not to sell them as advertised" (Minn. Stat. Ann. §325D.44, Subd. 1(9)); and

(d) "[e]ngag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding" (Minn. Stat. Ann. §325D.44, Subd. 1(13)).

3156. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Minnesota UDTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3157. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Minnesota UDTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

3158. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3159. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3160. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3161. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3162. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Minnesota UDTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3163. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Minnesota UDTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3164. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3165. As a result of Defendants' violations of the Minnesota UDTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding costs, attorneys' fees, and any other just and proper relief available under the Minnesota UDTPA.

COUNT 147
Strict Products Liability/Failure to Warn
(Against All Defendants)

3166. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3167. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against all Defendants.

3168. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3169. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3170. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3171. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3172. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3173. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3174. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3175. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3176. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3177. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3178. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3179. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3180. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3181. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3182. 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.

3183. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3184. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3185. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3186. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3187. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3188. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3189. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 148
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3190. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3191. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against all Defendants.

3192. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3193. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3194. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3195. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3196. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3197. Manufacturer Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3198. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3199. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3200. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3201. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3202. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3203. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 149
Strict Products Liability/Design Defect
(Against All Defendants)

3204. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3205. This cause of action is brought on behalf of the Minnesota Class (for the purpose of this section, "Class") against all Defendants.

3206. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At

all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3207. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3208. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3209. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3210. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3211. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3212. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3213. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3214. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3215. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3216. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3217. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3218. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-

Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3219. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3220. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3221. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3222. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3223. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

25. Causes of Action Brought on Behalf of the Mississippi Class

COUNT 150
Breach of Express Warranty
(Miss. Code Ann. §75-2-313)
(Against All Defendants)

3224. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3225. This cause of action is brought on behalf of the Mississippi Class (for the purpose of this section, "Class") against all Defendants.

3226. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Miss. Code Ann. §75-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Miss. Code Ann. §75-2-313.

3227. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Miss. Code Ann. §75-2-313.

3228. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3229. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3230. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3231. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3232. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3233. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3234. Plaintiffs and the Class members gave Defendants reasonable notice of their breaches of express warranty and an opportunity to cure such breaches or, in the alternative, were not required to do so because such an opportunity would be unnecessary and futile given that Defendants are unable to cure the defect in Ranitidine-Containing Products.

3235. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 151
Breach of Implied Warranty
(Miss. Code Ann. §75-2-314)
(Against All Defendants)

3236. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3237. This cause of action is brought on behalf of the Mississippi Class (for the purpose of this section, "Class") against all Defendants.

3238. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3239. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Miss. Code Ann. §75-2-314.

3240. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3241. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3242. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3243. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3244. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3245. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 152
Products Liability/Failure to Warn
(Miss. Code Ann. §11-1-63)
(Against All Defendants)

3246. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3247. This cause of action is brought on behalf of the Mississippi Class (for the purpose of this section, "Class") against all Defendants.

3248. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3249. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3250. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3251. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3252. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3253. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3254. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3255. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3256. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3257. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3258. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3259. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3260. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3261. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3262. 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.

3263. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3264. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3265. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3266. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3267. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3268. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3269. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 153
Products Liability/Manufacturing Defect
(Miss. Code Ann. §11-1-63)
(Against All Defendants)

3270. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3271. This cause of action is brought on behalf of the Mississippi User Class (for the purpose of this section, "Class") against all Defendants.

3272. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3273. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3274. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3275. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3276. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3277. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3278. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3279. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3280. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3281. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3282. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3283. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 154
Products Liability/Design Defect
(Miss. Code Ann. §11-1-63)
(Against All Defendants)

3284. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3285. This cause of action is brought on behalf of the Mississippi Class (for the purpose of this section, "Class") against all Defendants.

3286. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3287. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3288. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3289. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3290. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3291. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3292. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3293. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3294. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3295. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3296. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3297. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3298. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3299. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3300. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3301. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3302. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3303. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

26. Causes of Action Brought on Behalf of the Missouri Class

COUNT 155
Breach of Express Warranty
(Mo. Ann. Stat. §400.2-313)
(Against All Defendants)

3304. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3305. This cause of action is brought on behalf of the Missouri Class (for the purpose of this section, "Class") against all Defendants.

3306. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Mo. Ann. Stat. §400.2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Mo. Ann. Stat. §400.2-313.

3307. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Mo. Ann. Stat. §400.2-313.

3308. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3309. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3310. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3311. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3312. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3313. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3314. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 156
Breach of Implied Warranty
(Mo. Ann. Stat. §400.2-314)
(Against All Defendants)

3315. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3316. This cause of action is brought on behalf of the Missouri Class (for the purpose of this section, "Class") against all Defendants.

3317. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3318. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Mo. Ann. Stat. §400.2-314.

3319. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3320. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3321. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3322. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3323. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3324. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 157
Violation of the Missouri Merchandising Practices Act
(Mo. Ann. Stat. §407.010, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3325. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3326. This cause of action is brought on behalf of the Missouri Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3327. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Mo. Ann. Stat. §407.010(5).

3328. Defendants were and are engaged in "[t]rade or commerce" within the meaning of Mo. Ann. Stat. §407.010(7).

3329. The Missouri Merchandising Practices Act ("Missouri MPA") prohibits "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Ann. Stat. §407.020(1).

3330. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Missouri MPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3331. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Missouri MPA.

3332. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3333. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3334. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3335. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3336. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair or deceptive practices under the Missouri MPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the

Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3337. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Missouri MPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3338. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3339. As a result of Defendants' violations of the Missouri MPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Missouri MPA.

COUNT 158
Strict Products Liability/Failure to Warn
(Against All Defendants)

3340. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3341. This cause of action is brought on behalf of the Missouri Class (for the purpose of this section, "Class") against all Defendants.

3342. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3343. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3344. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3345. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3346. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3347. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3348. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3349. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3350. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3351. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3352. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3353. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3354. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3355. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3356. 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.

3357. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3358. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3359. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3360. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3361. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3362. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3363. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 159
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3364. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3365. This cause of action is brought on behalf of the Missouri Class (for the purpose of this section, "Class") against all Defendants.

3366. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3367. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3368. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3369. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3370. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3371. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3372. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3373. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3374. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3375. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3376. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3377. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 160
Strict Products Liability/Design Defect
(Against All Defendants)

3378. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3379. This cause of action is brought on behalf of the Missouri Class (for the purpose of this section, "Class") against all Defendants.

3380. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3381. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3382. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3383. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3384. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3385. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3386. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3387. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3388. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3389. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3390. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3391. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3392. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3393. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3394. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3395. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3396. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3397. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

27. Causes of Action Brought on Behalf of the Montana Class

COUNT 161
Breach of Express Warranty
(Mont. Code Ann. §30-2-313)
(Against All Defendants)

3398. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3399. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against all Defendants.

3400. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Mont. Code Ann. §30-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Mont. Code Ann. §30-2-313.

3401. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Mont. Code Ann. §30-2-313.

3402. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3403. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3404. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3405. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3406. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3407. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3408. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 162
Breach of Implied Warranty
(Mont. Code Ann. §30-2-314)
(Against All Defendants)

3409. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3410. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against all Defendants.

3411. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3412. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Mont. Code Ann. §30-2-314.

3413. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3414. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3415. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3416. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3417. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3418. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 163
Violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1973
(Mont. Code Ann. §30-14-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3419. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3420. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3421. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Mont. Code Ann. §30-14-102(6).

3422. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Mont. Code Ann. §30-14-102(1).

3423. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Mont. Code Ann. §30-14-102(8).

3424. The Montana Unfair Trade Practices and Consumer Protection Act of 1973 ("Montana CPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. §30-14-103.

3425. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the Montana CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3426. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the Montana CPA.

3427. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3428. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3429. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3430. Plaintiffs and the Class members relied on Defendants' misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendants' misrepresentations, omissions, and concealments were made.

3431. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3432. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Montana CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing Products because they possessed exclusive knowledge, they intentionally concealed the dangers of Ranitidine-Containing Products from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3433. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Montana CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3434. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3435. As a result of Defendants' violations of the Montana CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Montana CPA.

COUNT 164
Strict Products Liability/Failure to Warn
(Against All Defendants)

3436. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3437. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against all Defendants.

3438. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3439. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3440. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3441. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3442. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3443. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3444. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3445. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3446. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3447. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3448. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3449. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3450. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3451. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3452. 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.

3453. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3454. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3455. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3456. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3457. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3458. Accordingly, Plaintiffs and the members of the Class would not: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3459. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 165
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3460. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3461. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against all Defendants.

3462. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3463. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3464. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3465. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3466. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3467. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3468. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3469. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3470. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3471. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3472. Accordingly, Plaintiffs and the members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3473. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 166
Strict Products Liability/Design Defect
(Against All Defendants)

3474. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3475. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against all Defendants.

3476. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3477. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3478. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3479. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3480. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3481. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3482. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3483. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3484. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3485. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3486. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3487. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3488. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3489. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3490. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3491. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3492. Accordingly, Plaintiffs and the members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3493. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 167
Medical Monitoring
(Against All Defendants)

3494. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3495. This cause of action is brought on behalf of the Montana Class (for the purpose of this section, "Class") against all Defendants.

3496. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

3497. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

3498. Defendants breached these duties by, *inter alia*, failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to

know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

3499. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

3500. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

3501. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

3502. Plaintiffs and members of the Class 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.

3503. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

3504. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

3505. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

3506. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

3507. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

3508. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

3509. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

3510. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

3511. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

28. Causes of Action Brought on Behalf of the Nebraska Class

COUNT 168
Breach of Express Warranty
(Neb. Rev. Stat. Ann. §2-313)
(Against All Defendants)

3512. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3513. This cause of action is brought on behalf of the Nebraska Class (for the purpose of this section, "Class") against all Defendants.

3514. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Neb. Rev. Stat. Ann. §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Neb. Rev. Stat. Ann. §2-313.

3515. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Neb. Rev. Stat. Ann. §2-313.

3516. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3517. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3518. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3519. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the

Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3520. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3521. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3522. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 169
Breach of Implied Warranty
(Neb. Rev. Stat. Ann. §2-314)
(Against All Defendants)

3523. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3524. This cause of action is brought on behalf of the Nebraska Class (for the purpose of this section, "Class") against all Defendants.

3525. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3526. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Neb. Rev. Stat. Ann. §2-314.

3527. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3528. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3529. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3530. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3531. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3532. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 170
Violation of the Nebraska Consumer Protection Act
(Neb. Rev. Stat. Ann. §59-1601, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3533. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3534. This cause of action is brought on behalf of the Nebraska Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3535. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Neb. Rev. Stat. Ann. §59-1601(1).

3536. The Ranitidine-Containing Products are "[a]ssets" within the meaning of Neb. Rev. Stat. Ann. §59-1601(3).

3537. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Neb. Rev. Stat. Ann. §59-1601(2).

3538. The Nebraska Consumer Protection Act ("Nebraska CPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Neb. Rev. Stat. Ann. §59-1602.

3539. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Nebraska CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3540. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Nebraska CPA.

3541. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3542. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were

likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3543. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3544. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3545. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Nebraska CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3546. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Nebraska CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3547. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3548. As a result of Defendants' violations of the Nebraska CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Nebraska CPA.

COUNT 171
Strict Products Liability/Failure to Warn
(Against All Defendants)

3549. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3550. This cause of action is brought on behalf of the Nebraska Class (for the purpose of this section, "Class") against all Defendants.

3551. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3552. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3553. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3554. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3555. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3556. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3557. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3558. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products.

Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3559. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3560. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3561. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3562. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3563. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3564. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3565. 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.

3566. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3567. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3568. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products,

Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3569. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3570. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3571. Accordingly, Plaintiffs and the Class members would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3572. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the Class members have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 172
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3573. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3574. This cause of action is brought on behalf of the Nebraska Class (for the purpose of this section, "Class") against all Defendants.

3575. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3576. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3577. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3578. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3579. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3580. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3581. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3582. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3583. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3584. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3585. Accordingly, Plaintiffs and the Class members would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3586. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the Class members have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 173Count II
Strict Products Liability/Design Defect
(Against All Defendants)

3587. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3588. This cause of action is brought on behalf of the Nebraska Class (for the purpose of this section, "Class") against all Defendants.

3589. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3590. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3591. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products,

including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3592. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3593. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3594. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3595. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3596. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3597. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3598. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3599. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3600. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3601. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3602. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid

(Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3603. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3604. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3605. Accordingly, Plaintiffs and the Class members would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3606. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and the Class members have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

29. Causes of Action Brought on Behalf of the Nevada Class

COUNT 174
Breach of Express Warranty
(Nev. Rev. Stat. Ann. §104.2313)
(Against All Defendants)

3607. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3608. This cause of action is brought on behalf of the Nevada Class (for the purpose of this section, "Class") against all Defendants.

3609. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Nev. Rev. Stat. Ann. §104.2313 and "sellers" of Ranitidine-Containing Products within the meaning of Nev. Rev. Stat. Ann. §104.2313.

3610. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Nev. Rev. Stat. Ann. §104.2313.

3611. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3612. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3613. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3614. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3615. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3616. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3617. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 175
Breach of Implied Warranty
(Nev. Rev. Stat. Ann. §104.2314)
(Against All Defendants)

3618. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3619. This cause of action is brought on behalf of the Nevada Class (for the purpose of this section, "Class") against all Defendants.

3620. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3621. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Nev. Rev. Stat. Ann. §104.2314.

3622. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3623. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3624. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3625. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3626. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3627. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 176
Violation of the Nevada Deceptive Trade Practices Act
(Nev. Rev. Stat. Ann. §598.0903, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3628. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3629. This cause of action is brought on behalf of the Nevada Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3630. The Nevada Deceptive Trade Practices Act ("Nevada DTPA"), prohibits the use of "'deceptive trade practices' . . . in the course of . . . business or occupation." Nev. Rev. Stat. Ann. §598.0915.

3631. The Nevada DTPA makes unlawful specific acts, including:

(a) "[k]nowingly mak[ing] a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease or a false representation as to the sponsorship, approval, status, affiliation or connection of a person therewith" (Nev. Rev. Stat. Ann. §598.0915(5));

(b) "[r]epresent[ing] that goods or services for sale or lease are of a particular standard, quality or grade, or that such goods are of a particular style or model, if he or she knows or should know that they are of another standard, quality, grade, style or model" (Nev. Rev. Stat. Ann. §598.0915(7));

(c) "[a]dvertis[ing] goods or services with intent not to sell or lease them as advertised" (Nev. Rev. Stat. Ann. §598.0915(9));

(d) "[k]nowingly mak[ing] any other false representation in a transaction" (Nev. Rev. Stat. Ann. §598.0915(15)); and

(e) "[f]ail[ing] to disclose a material fact in connection with the sale or lease of goods or services" (Nev. Rev. Stat. Ann. §598.0923(2)).

3632. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Nevada DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3633. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as

detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Nevada DTPA, including:

(a) representing that Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) failing to disclose the NDMA danger in connection with the sale of the Ranitidine-Containing Products; and

(e) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

3634. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3635. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3636. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3637. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3638. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Nevada DTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3639. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Nevada DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would

not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3640. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3641. As a result of Defendants' violations of the Nevada DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Nevada DTPA.

COUNT 177
Strict Products Liability/Failure to Warn
(Against All Defendants)

3642. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3643. This cause of action is brought on behalf of the Nevada Class (for the purpose of this section, "Class") against all Defendants.

3644. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3645. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3646. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3647. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3648. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3649. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including

Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3650. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3651. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3652. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3653. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3654. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3655. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3656. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3657. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3658. 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.

3659. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3660. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3661. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3662. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3663. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3664. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3665. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 178
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3666. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3667. This cause of action is brought on behalf of the Nevada Class (for the purpose of this section, "Class") against all Defendants.

3668. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3669. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3670. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3671. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3672. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3673. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3674. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3675. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3676. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3677. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3678. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3679. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 179
Strict Products Liability/Design Defect
(Against All Defendants)

3680. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3681. This cause of action is brought on behalf of the Nevada Class (for the purpose of this section, "Class") against all Defendants.

3682. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3683. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3684. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3685. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3686. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3687. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3688. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3689. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3690. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3691. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3692. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3693. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3694. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3695. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3696. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3697. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3698. Accordingly, Plaintiffs and members of the Class would not (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3699. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

30. Causes of Action Brought on Behalf of the New Hampshire Class

COUNT 180
Breach of Express Warranty
(N.H. Rev. Stat. Ann. §382-A:2-313)
(Against All Defendants)

3700. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3701. This cause of action is brought on behalf of the New Hampshire Class (for the purpose of this section, "Class") against all Defendants.

3702. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of N.H. Rev. Stat. Ann. §382-A:2-313 and "sellers" of Ranitidine-Containing Products within the meaning of N.H. Rev. Stat. Ann. §382-A:2-313.

3703. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of N.H. Rev. Stat. Ann. §382-A:2-313.

3704. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3705. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3706. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3707. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3708. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3709. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3710. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 181
Breach of Implied Warranty
(N.H. Rev. Stat. Ann. §382-A:2-314)
(Against All Defendants)

3711. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3712. This cause of action is brought on behalf of the New Hampshire Class (for the purpose of this section, "Class") against all Defendants.

3713. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3714. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.H. Rev. Stat. Ann. §382-A:2-314.

3715. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3716. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3717. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3718. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3719. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3720. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 182
Violation of the New Hampshire Consumer Protection Act
(N.H. Rev. Stat. Ann. §358-A:1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3721. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3722. This cause of action is brought on behalf of the New Hampshire Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3723. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of N.H. Rev. Stat. Ann. §358-A:1(I).

3724. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of N.H. Rev. Stat. Ann. §358-A:1(II).

3725. The New Hampshire Consumer Protection Act ("New Hampshire CPA") prohibits "any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce." N.H. Rev. Stat. Ann. §358-A:2.

3726. The New Hampshire CPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (N.H. Rev. Stat. Ann. §358-A:2(V));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." (N.H. Rev. Stat. Ann. §358-A:2(VII)); and

(c) "[a]dvertising goods or services with intent not to sell them as advertised." (N.H. Rev. Stat. Ann. §358-A:2(IX)).

3727. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the New Hampshire CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3728. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New Hampshire CPA, including:

(a) representing that Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not; and

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised.

3729. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3730. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3731. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3732. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3733. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the New Hampshire CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed

exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3734. Plaintiffs and the Class members were aggrieved by Defendants' violations of New Hampshire CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3735. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3736. As a result of Defendants' violations of the New Hampshire CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New Hampshire CPA.

COUNT 183
Strict Products Liability/Failure to Warn
(Against All Defendants)

3737. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3738. This cause of action is brought on behalf of the New Hampshire Class (for the purpose of this section, "Class") against all Defendants.

3739. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3740. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3741. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3742. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3743. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3744. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3745. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3746. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3747. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3748. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3749. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3750. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3751. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3752. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3753. 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.

3754. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3755. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3756. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3757. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3758. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3759. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3760. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 184
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3761. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3762. This cause of action is brought on behalf of the New Hampshire Class (for the purpose of this section, "Class") against all Defendants.

3763. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3764. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3765. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3766. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3767. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3768. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3769. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3770. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3771. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3772. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3773. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3774. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 185
Strict Products Liability/Design Defect
(Against All Defendants)

3775. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3776. This cause of action is brought on behalf of the New Hampshire Class (for the purpose of this section, "Class") against all Defendants.

3777. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3778. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3779. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3780. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3781. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3782. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3783. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3784. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3785. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3786. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3787. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3788. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3789. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3790. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3791. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3792. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3793. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3794. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

31. Causes of Action Brought on Behalf of the New Jersey Class

COUNT 186
Breach of Express Warranty
(N.J. Stat. Ann. §12A:2-313)
(Against All Defendants)

3795. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3796. This cause of action is brought on behalf of the New Jersey Class (for the purpose of this section, "Class") against all Defendants.

3797. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of N.J. Stat. Ann. §12A:2-313 and "sellers" of Ranitidine-Containing Products within the meaning of N.J. Stat. Ann. §12A:2-313.

3798. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of N.J. Stat. Ann. §12A:2-313.

3799. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3800. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3801. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3802. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3803. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3804. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3805. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 187
Breach of Implied Warranty
(N.J. Stat. Ann. §12A:2-314)
(Against All Defendants)

3806. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3807. This cause of action is brought on behalf of the New Jersey Class (for the purpose of this section, "Class") against all Defendants.

3808. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3809. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.J. Stat. Ann. §12A:2-314.

3810. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3811. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3812. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3813. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3814. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3815. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 188
Violation of the New Jersey Consumer Fraud Act
(N.J. Stat. Ann. §56:8-1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3816. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3817. This cause of action is brought on behalf of the New Jersey Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3818. Defendants, Plaintiffs, and the Class members are "person[s]" within the meaning of N.J. Stat. Ann. §56:8-1(d).

3819. The Ranitidine-Containing Products are "merchandise" within the meaning of N.J. Stat. Ann. §56:8-1(c).

3820. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the New Jersey Consumer Fraud Act ("New Jersey CFA") by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above. N.J. Stat. Ann. §56:8-1, *et seq.*

3821. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New Jersey CFA.

3822. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3823. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein,

had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3824. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3825. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3826. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the New Jersey CFA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3827. Plaintiffs and the Class members were aggrieved by Defendants' violations of the New Jersey CFA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3828. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3829. As a result of Defendants' violations of the New Jersey CFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New Jersey CFA.

COUNT 189
Products Liability/Failure to Warn
New Jersey Products Liability Act
(Against All Defendants)

3830. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3831. This cause of action is brought on behalf of the New Jersey Class (for the purpose of this section, "Class") against all Defendants.

3832. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3833. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3834. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3835. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3836. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3837. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3838. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3839. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products.

Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3840. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3841. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3842. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller exercising reasonable and due care.

3843. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3844. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3845. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3846. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3847. 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.

3848. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3849. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

3850. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3851. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3852. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3853. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3854. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 190
Products Liability/Manufacturing Defect
New Jersey Products Liability Act
(Against All Defendants)

3855. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3856. This cause of action is brought on behalf of the New Jersey Class (for the purpose of this section, "Class") against all Defendants.

3857. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3858. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3859. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3860. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3861. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3862. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3863. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

3864. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3865. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3866. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3867. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3868. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3869. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 191
Products Liability/Design Defect
New Jersey Products Liability Act
(Against All Defendants)

3870. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3871. This cause of action is brought on behalf of the New Jersey Class (for the purpose of this section, "Class") against all Defendants.

3872. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including

Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3873. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3874. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3875. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3876. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous

to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3877. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

3878. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3879. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3880. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3881. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3882. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3883. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3884. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3885. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3886. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3887. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3888. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3889. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3890. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

32. Causes of Action Brought on Behalf of the New Mexico Class

COUNT 192
Breach of Express Warranty
(N.M. Stat. Ann. §55-2-313)
(Against All Defendants)

3891. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3892. This cause of action is brought on behalf of the New Mexico Class (for the purpose of this section, "Class") against all Defendants.

3893. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of N.M. Stat. Ann. §55-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of N.M. Stat. Ann. §55-2-313.

3894. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of N.M. Stat. Ann. §55-2-313.

3895. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or

promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3896. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3897. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3898. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and

Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3899. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3900. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3901. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 193
Breach of Implied Warranty
(N.M. Stat. Ann. §55-2-314)
(Against All Defendants)

3902. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3903. This cause of action is brought on behalf of the New Mexico Class (for the purpose of this section, "Class") against all Defendants.

3904. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

3905. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.M. Stat. Ann. §55-2-314.

3906. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

3907. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

3908. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

3909. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

3910. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

3911. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 194
Violation of the New Mexico Unfair Trade Practices Act
(N.M. Stat. Ann. §57-12-1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

3912. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3913. This cause of action is brought on behalf of the New Mexico Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

3914. Defendants, Plaintiffs, and the Class members are "person[s]" within the meaning of N.M. Stat. Ann. §57-12-2(A).

3915. Defendants were and are engaged in "trade" or "commerce" within the meaning of N.M. Stat. Ann. §57-12-2(C).

3916. The New Mexico Unfair Trade Practices Act ("New Mexico UTPA") makes unlawful "a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services . . . by a person in the regular course of the person's trade or commerce, that may, tends to or does deceive or mislead any person." N.M. Stat. Ann. §57-12-2(D). The New Mexico UTPA also makes unlawful "an act or practice in connection with the sale, lease, rental, or loan, or in connection with the offering for sale, lease, rental or loan, of any goods or services, . . . that to a person's detriment: (1) takes advantage of the lack of knowledge, ability, experience or capacity

of a person to a grossly unfair degree; or (2) results in a gross disparity between the value received by a person and the price paid." N.M. Stat. Ann. §57-12-2(E).

3917. The New Mexico UTPA makes unlawful specific acts, including:

(a) "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have" (N.M. Stat. Ann. §57-12-2(D)(5));

(b) "representing that goods or services are of a particular standard, quality or grade or that goods are of a particular style or model if they are of another" (N.M. Stat. Ann. §57-12-2(D)(7)); and

(c) "using exaggeration, innuendo or ambiguity as to a material fact . . . if doing so deceives or tends to deceive" (N.M. Stat. Ann. §57-12-2(D)(14)).

3918. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the New Mexico UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

3919. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New Mexico UTPA, including:

(a) representing that Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) using exaggeration and/or failing to state the material facts concerning the Ranitidine-Containing Products in a manner that tended to deceive; and

(d) acting in a manner that resulted in a gross disparity between the true value of the Ranitidine-Containing Products and the price paid.

3920. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

3921. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

3922. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

3923. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

3924. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the New Mexico UTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective,

unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

3925. Plaintiffs and the Class members were aggrieved by Defendants' violations of the New Mexico UTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

3926. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

3927. As a result of Defendants' violations of the New Mexico UTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New Mexico UTPA.

COUNT 195
Strict Products Liability/Failure to Warn
(Against All Defendants)

3928. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3929. This cause of action is brought on behalf of the New Mexico Class (for the purpose of this section, "Class") against all Defendants.

3930. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

3931. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

3932. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

3933. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

3934. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

3935. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

3936. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

3937. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

3938. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

3939. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

3940. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

3941. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

3942. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

3943. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

3944. 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.

3945. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

3946. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.

3947. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

3948. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

3949. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3950. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3951. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 196
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

3952. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3953. This cause of action is brought on behalf of the New Mexico Class (for the purpose of this section, "Class") against all Defendants.

3954. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

3955. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

3956. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3957. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

3958. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

3959. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

3960. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

3961. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

3962. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

3963. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3964. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3965. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 197
Strict Products Liability/Design Defect
(Against All Defendants)

3966. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3967. This cause of action is brought on behalf of the New Mexico Class (for the purpose of this section, "Class") against all Defendants.

3968. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

3969. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

3970. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

3971. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

3972. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

3973. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

3974. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

3975. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

3976. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

3977. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

3978. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

3979. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

3980. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

3981. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

3982. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

3983. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

3984. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

3985. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

33. Causes of Action Brought on Behalf of the New York Class

COUNT 198
Breach of Express Warranty
(N.Y. U.C.C. Law §2-313)
(Against All Defendants)

3986. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3987. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against all Defendants.

3988. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of N.Y. U.C.C. Law §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of N.Y. U.C.C. Law §2-313.

3989. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of N.Y. U.C.C. Law §2-313.

3990. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

3991. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

3992. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

3993. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

3994. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

3995. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

3996. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

3997. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 199
Breach of Implied Warranty
(N.Y. U.C.C. Law §2-314)
(Against All Defendants)

3998. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

3999. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against all Defendants.

4000. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4001. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.Y. U.C.C. Law §2-314.

4002. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4003. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4004. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4005. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4006. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4007. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 200
Violation of New York Deceptive Acts and Practices Act
(N.Y. Gen. Bus. Law §349)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4008. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4009. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4010. Plaintiffs and the Class members are "person[s]" within the meaning of N.Y. Gen. Bus. Law §349(h). Defendants are each a "person, firm, corporation or association" within the meaning of N.Y. Gen. Bus. Law §349(b).

4011. The New York Deceptive Acts and Practices Act ("New York DAPA") prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law §349(a).

4012. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the New York DAPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4013. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New York DAPA.

4014. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4015. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4016. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4017. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4018. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the New York DAPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4019. Plaintiffs and the Class members were aggrieved by Defendants' violations of the New York DAPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and

failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4020. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4021. As a result of Defendants' violations of the New York DAPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New York DAPA.

COUNT 201
Violation of the New York False Advertising Act
(N.Y. Gen. Bus. Law §350)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4022. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4023. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4024. Defendants were and are engaged in "conduct of business, trade or commerce" within the meaning of N.Y. Gen. Bus. Law §350.

4025. The New York False Advertising Act ("New York FAA") prohibits "[f]alse advertising in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law §350. False advertising includes "advertising, including labeling, of a commodity . . . if such advertising is

misleading in a material respect," taking into account "the extent to which the advertising fails to reveal facts material in the light of . . . representations [made] with respect to the commodity." N.Y. Gen. Bus. Law §350-a(1).

4026. Defendants caused to be made or disseminated through New York and the United States, through advertising, marketing, and other publications, statements that were untrue or misleading, and which were known, or which by exercise of reasonable care should have been known to Defendants, to be untrue and misleading to consumers, including Plaintiffs and the Class members.

4027. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the New York FAA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4028. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New York FAA.

4029. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4030. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein,

had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4031. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4032. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4033. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the New York FAA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4034. Plaintiffs and the Class members were aggrieved by Defendants' violations of the New York FAA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4035. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4036. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

4037. As a result of Defendants' violations of the New York FAA, as alleged herein, Plaintiffs and the New York Class members seek an order enjoining Defendants' unfair or

deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New York FAA.

COUNT 202
Strict Products Liability/Failure to Warn
(Against All Defendants)

4038. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4039. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against all Defendants.

4040. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4041. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4042. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4043. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4044. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4045. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4046. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4047. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4048. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4049. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4050. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4051. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4052. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4053. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4054. 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.

4055. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4056. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4057. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4058. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4059. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4060. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4061. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 203
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

4062. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4063. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against all Defendants.

4064. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4065. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4066. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4067. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4068. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4069. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4070. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4071. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4072. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4073. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4074. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4075. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 204
Strict Products Liability/Design Defect
(Against All Defendants)

4076. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4077. This cause of action is brought on behalf of the New York Class (for the purpose of this section, "Class") against all Defendants.

4078. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4079. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4080. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4081. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4082. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4083. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4084. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4085. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4086. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4087. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4088. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4089. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4090. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4091. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4092. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4093. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4094. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4095. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

34. Causes of Action Brought on Behalf of the North Carolina Class

COUNT 205
Breach of Express Warranty
(N.C. Gen. Stat. Ann. §25-2-313)
(Against All Defendants)

4096. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4097. This cause of action is brought on behalf of the North Carolina Class (for the purpose of this section, "Class") against all Defendants.

4098. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of N.C. Gen. Stat. Ann. §25-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of N.C. Gen. Stat. Ann. §25-2-313.

4099. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of N.C. Gen. Stat. Ann. §25-2-313.

4100. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4101. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4102. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4103. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

4104. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4105. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4106. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4107. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 206
Breach of Implied Warranty
(N.C. Gen. Stat. Ann. §25-2-314)
(Against All Defendants)

4108. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4109. This cause of action is brought on behalf of the North Carolina Class (for the purpose of this section, "Class") against all Defendants.

4110. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4111. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.C. Gen. Stat. Ann. §25-2-314.

4112. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4113. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4114. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4115. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4116. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4117. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 207
Violation of the North Carolina Unfair and Deceptive Trade Practices Act
(N.C. Gen. Stat. Ann. §75-1.1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4118. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4119. This cause of action is brought on behalf of the North Carolina Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4120. Defendants were and are engaged in "commerce" within the meaning of N.C. Gen. Stat. Ann. §75-1.1(b).

4121. The North Carolina Unfair and Deceptive Trade Practices Act ("North Carolina UDTPA") prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce," N.C. Gen. Stat. Ann. §75-1.1(a), and provides a private right of action for any person injured "by reason of any act or thing done by any other person, firm or corporation in violation of" the law. N.C. Gen. Stat. Ann. §75-16.

4122. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the North Carolina UDTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4123. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the North Carolina UDTPA.

4124. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4125. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4126. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4127. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4128. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the North Carolina UDTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4129. Plaintiffs and the Class members were aggrieved by Defendants' violations of the North Carolina UDTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and

failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4130. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4131. As a result of Defendants' violations of the North Carolina UDTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the North Carolina UDTPA.

COUNT 208
Product Liability-Negligence
(Against All Defendants)

4132. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4133. This cause of action is brought on behalf of the North Carolina Class (for the purpose of this section, "Class") against all Defendants.

4134. Defendants, directly or indirectly, caused Ranitidine-Containing Products to be sold, distributed, marketed, promoted, and/or used by Plaintiffs and members of the Class.

4135. At all relevant times, Defendants had a duty to exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products so

as to prevent its product from harming others, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous.

4136. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the known or foreseeable risks of using Ranitidine-Containing Products as directed and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products when used as intended – in particular, their ability to transform into carcinogenic compound, NDMA. Defendants had a duty to warn foreseeable OTC consumers and foreseeable prescription users' physicians.

4137. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known—of the hazards and dangers associated with Ranitidine-Containing Products when used as intended. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

4138. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that the NDMA in Ranitidine-Containing Products could foreseeably cause or be associated with Plaintiffs' and Class members' injuries and, thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and Class members.

4139. At the time Ranitidine-Containing Products left Defendants' control, the lack of adequate warning created an unreasonably dangerous condition that Defendants knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to foreseeable users and consumers.

4140. Additionally, after Ranitidine-Containing Products left Defendants' control, Defendants became aware of or in the exercise of ordinary care should have known of additional information indicating that Ranitidine-Containing Products posed a substantial risk of harm to foreseeable users.

4141. At the time Ranitidine-Containing Products left Defendants' control, Defendants unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of Ranitidine-Containing Products.

4142. Additionally, at the time Ranitidine-Containing Products left Defendants' control, the drugs' design and/or formulation was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

4143. Defendants reasonably could have eliminated Ranitidine-Containing Products' inherent toxicity without compromising the drugs' usefulness by manufacturing Ranitidine-Containing Products with a different formulation

4144. Defendants had no reason to believe that foreseeable users and consumers of Ranitidine-Containing Products, including Plaintiffs and Class members, were aware of the potential for ranitidine to transform into NDMA and/or of the magnitude of the risks associated with Ranitidine-Containing Products when used as intended.

4145. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products in that Defendants manufactured and produced defective Ranitidine-

Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects when put to their intended use; knew or had reason to know that consumers were unaware of the risks related to NDMA in Ranitidine-Containing Products; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

4146. Outside of the labeling context, Defendants were negligent in their promotion of Ranitidine-Containing Products by failing to prevent foreseeable harm by disclosing material risk information as part of their promotion and marketing of Ranitidine-Containing Products through the media of internet, television, print advertisements, etc. Nothing prevented Defendants from presenting the truth concerning the risks associated with the use of Ranitidine-Containing Products in their promotional efforts. Indeed, Defendants had a duty to disclose the truth regarding those risks, outside of the context of labeling.

4147. Despite their ability and ample means to investigate, study, and test their products and provide adequate warnings, Defendants failed to do so. Instead, Defendants wrongfully concealed information and made further false and/or misleading statements concerning the safety and use of Ranitidine-Containing Products.

4148. Defendants' acts of negligence include, but are not limited to:

(a) Manufacturing, producing, formulating, creating, developing, designing, selling, and/or distributing Ranitidine-Containing Products without thorough and adequate pre- and post-market testing;

(b) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Ranitidine-Containing Products

while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Ranitidine-Containing Products and the carcinogenic potential of NDMA created in the human body as a result of ingesting Ranitidine-Containing Products, and, consequently, the risk of serious harm associated with human use of Ranitidine-Containing Products;

(c) Failing to undertake sufficient studies and conduct necessary tests to determine whether Ranitidine-Containing Products were safe for their intended consumer use;

(d) Failing to exercise reasonable and prudent care in the design, research, manufacture, and development of Ranitidine-Containing Products to avoid the risk of serious harm associated with the prevalent use of Ranitidine-Containing Products;

(e) Failing to design and manufacture Ranitidine-Containing Products to ensure they were at least as safe and effective as other medications on the market intended to treat the same symptoms;

(f) Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use Ranitidine-Containing Products;

(g) Failing to disclose to Plaintiffs and Class members, consumers, and the general public that use of Ranitidine-Containing Products presented severe risks of cancer;

(h) Failing to warn Plaintiffs and members of the Class, consumers, and the general public that the products' risk of harm was unreasonable and that safer and effective alternatives were available;

(i) Failing to warn of or disclose Ranitidine-Containing Products' unreasonable risk to prescribing physicians of foreseeable users;

(j) Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of Ranitidine-Containing Products' side effects;

(k) Representing by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public that Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew, or should have known, the products were not safe for their intended purpose;

(l) Declining to make or propose any changes to Ranitidine-Containing Products' labeling or other promotional materials that would alert

consumers and the general public, including Plaintiffs and Class members, of the risks of Ranitidine-Containing Products;

(m) Advertising, marketing, and recommending use of the Zantac products, while concealing and failing to disclose or warn of the dangers known by Defendants to be associated with or caused by the use of or exposure to Ranitidine-Containing Products;

(n) Continuing to disseminate information to consumers, which indicate or imply that Defendants' Ranitidine-Containing Products are safe for regular consumer use; and/or

(o) Continuing the manufacture and sale of Ranitidine-Containing Products with the knowledge that such products were unreasonably unsafe and dangerous.

4149. Defendants were also negligent in that they labeled Ranitidine-Containing Products in a false and misleading manner that omitted any mention of the drugs' propensity to expose users to NDMA and in that they failed to suggest or recommend a manner of using Ranitidine-Containing Products so that they are not dangerous to users' and consumers' health when used as labeled and directed, thereby manufacturing, repackaging, offering for sale, delivering, and/or holding misbranded drugs in violation of 21 U.S.C. §§331, 352(a)(1), and 352(j) and N.C. Gen. Stat. Ann. §§106-122(1) and -134(1), (10).

4150. Defendants further breached their duty of care and were negligent in that while representing carcinogenic Ranitidine-Containing Products as safe, Defendants failed to employ manufacturing methods that ensured Ranitidine-Containing Products met the quality and purity characteristics they purported to possess, thereby manufacturing, repackaging, offering for sale, selling, delivering, and/or holding adulterated drugs in violation of 21 U.S.C. §§331 and 351(a)(2)(B) and N.C. Gen. Stat. Ann. §§106-122(1) and -133(1)(e).

4151. Defendants' duties as set forth in the above-mentioned statutes parallel their common-law duty to exercise reasonable care in the manufacture and labeling of Ranitidine-Containing Products.

4152. The North Carolina and United States legislatures designed the above-mentioned statutes to bolster consumer protection against dangerous pharmaceutical products and to supplement common-law liability for manufacturers of adulterated or misbranded drugs.

4153. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in North Carolina, are within the specific class of persons that the above-mentioned statutes were designed to protect.

4154. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

4155. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of and substantial factor in Plaintiffs' and Class members' purchasing and consuming improperly labeled and manufactured Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

4156. Additionally, Manufacturer Defendants breached their duty of care by failing to follow cGMPs in the storing, handling, and warehousing of Ranitidine-Containing Products, thereby increasing the risk that the drugs would produce NDMA during storage and/or transport, in that Defendants failed to ensure that Ranitidine-Containing Products were stored, handled, and warehoused under appropriate conditions of temperature, humidity, and light so that their identity, strength, quality, and purity was not adversely affected, in violation of the cGMPs set forth in 21 C.F.R. §211.142(b).

4157. Defendants knew—or in the exercise of reasonable care, should have known—that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries as a natural and probable result of Defendants' failure to exercise due care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

4158. Plaintiffs and members of the Class 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.

4159. But for Defendants' negligent acts, Plaintiffs and members of the Class would not have purchased or consumed Ranitidine-Containing Products.

4160. Had Defendants exercised due care to warn prescribers of Ranitidine-Containing Products' unreasonable danger, Plaintiffs' and Class members' physicians would not have prescribed them.

4161. Had Defendants disclosed and not misrepresented and concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs' and Class members' physicians would have read and heeded Defendants' warnings and would not have prescribed Ranitidine-Containing Products.

4162. Defendants' negligence was the natural and probable cause of Plaintiffs' and Class members' injuries. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would have read and heeded Defendants' warnings and would not have purchased or used the Ranitidine-Containing Products and, therefore, would have avoided injury.

4163. As a direct and proximate result of Defendants' failure to exercise reasonable care in designing, manufacturing, distributing, and testing their products so that the products would be

reasonably safe for foreseeable use, Plaintiffs and Class members been injured. They purchased and ingested Ranitidine-Containing Products that were unsafe for human consumption as a result of Defendants' failures. Had Defendants exercised due care to design, manufacture, distribute, and test a reasonably safe product, Plaintiffs and Class members would not have purchased or used the Ranitidine-Containing Products that exposed them to the carcinogenic NDMA.

4164. As a direct and proximate result of Defendants' failure to provide adequate warnings of Ranitidine-Containing Products' risks, Plaintiffs and Class members have been injured. They purchased Ranitidine-Containing Products that are unsafe for human consumption as a result of Defendants' misrepresentations, omissions, and concealment of and/or failure to timely disclose the dangerous safety and quality issues associated with the product caused by Defendants' conduct. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased or used Ranitidine-Containing Products.

4165. As a result of Defendants' negligent conduct, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4166. Accordingly, Plaintiffs and member of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4167. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and member of the Class have suffered physical injury, have a significantly increased risk of

developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

35. Causes of Action Brought on Behalf of the North Dakota Class

COUNT 209
Breach of Express Warranty
(N.D. Cent. Code Ann. §41-02-30)
(Against All Defendants)

4168. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4169. This cause of action is brought on behalf of the North Dakota Class (for the purpose of this section, "Class") against all Defendants.

4170. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of N.D. Cent. Code Ann. §41-02-30 and "sellers" of Ranitidine-Containing Products within the meaning of N.D. Cent. Code Ann. §41-02-30.

4171. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of N.D. Cent. Code Ann. §41-02-30.

4172. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4173. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4174. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4175. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4176. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably

discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4177. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4178. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 210
Breach of Implied Warranty
(N.D. Cent. Code Ann. §41-02-31)
(Against All Defendants)

4179. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4180. This cause of action is brought on behalf of the North Dakota Class (for the purpose of this section, "Class") against all Defendants.

4181. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4182. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.D. Cent. Code Ann. §41-02-31.

4183. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not

possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4184. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4185. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4186. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4187. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4188. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 211
Violation of the North Dakota Consumer Fraud Act
(N.D. Cent. Code Ann. §51-15-02)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4189. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4190. This cause of action is brought on behalf of the North Dakota Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4191. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of N.D. Cent. Code Ann. §51-15-01(4).

4192. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of N.D. Cent. Code Ann. §51-15-01(3).

4193. The North Dakota Consumer Fraud Act ("North Dakota CFA") prohibits "[t]he act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby." N.D. Cent. Code Ann. §51-15-02.

4194. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the North Dakota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4195. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such

drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the North Dakota CFA.

4196. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4197. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4198. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4199. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4200. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the North Dakota CFA in the course of their business.

Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4201. Plaintiffs and the Class members were aggrieved by Defendants' violations of the North Dakota CFA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4202. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4203. As a result of Defendants' violations of the North Dakota CFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the North Dakota CFA.

COUNT 212
Strict Products Liability/Failure to Warn
(Against All Defendants)

4204. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4205. This cause of action is brought on behalf of the North Dakota Class (for the purpose of this section, "Class") against all Defendants.

4206. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4207. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4208. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4209. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4210. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4211. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4212. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4213. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4214. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4215. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4216. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4217. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4218. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4219. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4220. 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.

4221. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4222. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4223. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4224. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4225. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4226. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4227. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 213
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

4228. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4229. This cause of action is brought on behalf of the North Dakota Class (for the purpose of this section, "Class") against all Defendants.

4230. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4231. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4232. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4233. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4234. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their

manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4235. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4236. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4237. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4238. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4239. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4240. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4241. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 214
Strict Products Liability/Design Defect
(Against All Defendants)

4242. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4243. This cause of action is brought on behalf of the North Dakota Class (for the purpose of this section, "Class") against all Defendants.

4244. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including

Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4245. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4246. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4247. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4248. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous

to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4249. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4250. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4251. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4252. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4253. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4254. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4255. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4256. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an

ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4257. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4258. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4259. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4260. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4261. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of

developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

36. Causes of Action Brought on Behalf of the Ohio Class

COUNT 215
Breach of Express Warranty
(Ohio Rev. Code Ann. §1302.26)
(Against All Defendants)

4262. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4263. This cause of action is brought on behalf of the Ohio Class (for the purpose of this section, "Class") against all Defendants.

4264. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Ohio Rev. Code Ann. §1302.26 and "sellers" of Ranitidine-Containing Products within the meaning of Ohio Rev. Code Ann. §1302.26.

4265. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Ohio Rev. Code Ann. §1302.26.

4266. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4267. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4268. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4269. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4270. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably

discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4271. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4272. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 216
Breach of Implied Warranty
(Ohio Rev. Code Ann. §1302.27)
(Against All Defendants)

4273. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4274. This cause of action is brought on behalf of the Ohio Class (for the purpose of this section, "Class") against all Defendants.

4275. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4276. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Ohio Rev. Code Ann. §1302.27.

4277. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not

possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4278. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4279. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4280. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4281. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4282. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 217
Strict Products Liability/Failure to Warn
Ohio Product Liability Act
(Against All Defendants)

4283. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4284. This cause of action is brought on behalf of the Ohio Class (for the purpose of this section, "Class") against all Defendants.

4285. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4286. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4287. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4288. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4289. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4290. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4291. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4292. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4293. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4294. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4295. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4296. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4297. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4298. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4299. 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.

4300. A manufacturer exercising reasonable care would have provided the warning or instruction to patients and healthcare provides, in light of the likelihood that the product would cause harm and in light of the likely seriousness of that harm.

4301. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4302. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4303. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4304. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4305. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4306. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4307. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 218
Strict Products Liability/Manufacturing Defect
Ohio Product Liability Act
(Against All Defendants)

4308. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4309. This cause of action is brought on behalf of the Ohio Class (for the purpose of this section, "Class") against all Defendants.

4310. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4311. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4312. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4313. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4314. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4315. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or healthcare providers.

4316. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4317. The Ranitidine-Containing Products deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards.

4318. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4319. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4320. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4321. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4322. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 219
Strict Products Liability/Design Defect
Ohio Product Liability Act
(Against All Defendants)

4323. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4324. This cause of action is brought on behalf of the Ohio Class (for the purpose of this section, "Class") against all Defendants.

4325. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including

Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4326. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4327. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4328. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4329. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous

to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4330. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4331. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4332. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4333. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4334. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4335. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4336. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4337. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an

ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4338. Accordingly, in the state of technical, scientific, and medical knowledge at the time the Ranitidine-Containing Products in question left the control of its manufacturer, the relevant aspect of that product was incapable of being made safe.

4339. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4340. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4341. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4342. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage,

subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4343. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

37. Causes of Action Brought on Behalf of the Oklahoma Class

COUNT 220
Breach of Express Warranty
(Okla. Stat. tit. 12A §2-313)
(Against All Defendants)

4344. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4345. This cause of action is brought on behalf of the Oklahoma Class (for the purpose of this section, "Class") against all Defendants.

4346. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Okla. Stat. tit. 12A §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Okla. Stat. tit. 12A §2-313.

4347. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Okla. Stat. tit. 12A §2-313.

4348. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for

their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4349. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4350. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4351. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4352. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4353. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4354. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 221
Breach of Implied Warranty
(Okla. Stat. tit. 12A §2-314)
(Against All Defendants)

4355. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4356. This cause of action is brought on behalf of the Oklahoma Class (for the purpose of this section, "Class") against all Defendants.

4357. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4358. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Okla. Stat. tit. 12A §2-314.

4359. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4360. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4361. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4362. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4363. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4364. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 222
Violation of the Oklahoma Consumer Protection Act
(Okla. Stat. tit. 15, §751, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4365. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4366. This cause of action is brought on behalf of the Oklahoma Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4367. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Okla. Stat. tit. 15, §752(1).

4368. Defendants were and are engaged in "[c]onsumer transaction[s]" within the meaning of Okla. Stat. tit. 15, §752(2).

4369. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Okla. Stat. tit. 15, §752(7).

4370. The Oklahoma Consumer Protection Act ("Oklahoma CPA") prohibits numerous unlawful acts, including misleading representations, false advertisements, and false statements. Okla. Stat. tit. 15, §753. The Oklahoma CPA defines "[d]eceptive trade practice" as "a misrepresentation, omission or other practice that has deceived or . . . mislead a person to the detriment of that person." Okla. Stat. tit. 15, §752(13). The Oklahoma CPA defines "[u]nfair trade practice" as "any practice which offends established public policy or if the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers." Okla. Stat. tit. 15, §752(14).

4371. The Oklahoma CPA makes unlawful specific acts, including:

(a) "[m]ak[ing] a false representation, knowingly or with reason to know, as to the characteristics, ingredients, uses, benefits, alterations, or quantities of the subject of a consumer transaction" (Okla. Stat. tit. 15, §753(5));

(b) "[r]epresent[ing], knowingly or with reason to know, that the subject of a consumer transaction is of a particular standard, style or model, if it is of another" (Okla. Stat. tit. 15, §753(7));

(c) "[a]dvertis[ing], knowingly or with reason to know, the subject of a consumer transaction with intent not to sell it as advertised" (Okla. Stat. tit. 15, §753(8)); and

(d) "[c]ommit[ing] an unfair or deceptive trade practice as defined in Section 752" (Okla. Stat. tit. 15, §753(20)).

4372. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Oklahoma CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4373. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Oklahoma CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

4374. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4375. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4376. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4377. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4378. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Oklahoma CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective,

unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4379. Plaintiffs and the Class members were aggrieved by Defendants' violations of Oklahoma CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4380. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4381. As a result of Defendants' violations of the Oklahoma CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or

practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Oklahoma CPA.

COUNT 223
Manufacturer's Products Liability/Failure to Warn
(Against All Defendants)

4382. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4383. This cause of action is brought on behalf of the Oklahoma Class (for the purpose of this section, "Class") against all Defendants.

4384. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4385. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4386. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain,

supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4387. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4388. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4389. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4390. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4391. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4392. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4393. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4394. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4395. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4396. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4397. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4398. 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.

4399. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4400. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to

comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4401. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4402. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4403. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4404. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4405. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 224
Manufacturer's Products Liability/Manufacturing Defect
(Against All Defendants)

4406. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4407. This cause of action is brought on behalf of the Oklahoma Class (for the purpose of this section, "Class") against all Defendants.

4408. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4409. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4410. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4411. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4412. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4413. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4414. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4415. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4416. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4417. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4418. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4419. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 225
Manufacturer's Products Liability/Design Defect
(Against All Defendants)

4420. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4421. This cause of action is brought on behalf of the Oklahoma Purchaser Class and the Oklahoma User Class (for the purpose of this section, "Class") against all Defendants.

4422. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4423. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4424. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4425. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4426. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4427. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4428. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4429. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4430. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4431. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4432. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4433. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4434. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4435. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4436. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4437. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4438. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4439. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

38. Causes of Action Brought on Behalf of the Oregon Class

COUNT 226
Breach of Express Warranty
(Or. Rev. Stat. Ann. §72.3130)
(Against All Defendants)

4440. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4441. This cause of action is brought on behalf of the Oregon Class (for the purpose of this section, "Class") against all Defendants.

4442. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Or. Rev. Stat. Ann. §72.3130 and "sellers" of Ranitidine-Containing Products within the meaning of Or. Rev. Stat. Ann. §72.3130.

4443. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Or. Rev. Stat. Ann. §72.3130.

4444. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4445. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4446. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4447. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4448. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4449. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4450. Plaintiffs and the Class members gave Defendants reasonable notice of their breaches of express warranty and an opportunity to cure such breaches or, in the alternative, were not required to do so because such an opportunity would be unnecessary and futile given that Defendants are unable to cure the defect in Ranitidine-Containing Products.

4451. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 227
Breach of Implied Warranty
(Or. Rev. Stat. Ann. §72.3140)
(Against All Defendants)

4452. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4453. This cause of action is brought on behalf of the Oregon Class (for the purpose of this section, "Class") against all Defendants.

4454. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4455. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Or. Rev. Stat. Ann. §72.3140.

4456. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4457. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4458. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4459. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4460. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4461. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 228
Violation of the Oregon Unlawful Trade Practices Act
(Or. Rev. Stat. Ann. §646.605, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4462. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4463. This cause of action is brought on behalf of the Oregon Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4464. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Or. Rev. Stat. Ann. §646.605(4).

4465. The Ranitidine-Containing Products are "goods" within the meaning of Or. Rev. Stat. Ann. §646.605(6).

4466. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Or. Rev. Stat. Ann. §646.605(8).

4467. The Oregon Unlawful Trade Practices Act ("Oregon UTPA") prohibits "unlawful practice . . . in the course of the person's business." Or. Rev. Stat. Ann. §646.608(1).

4468. The Oregon UTPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that real estate, goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that the real estate, goods or services do not have" (Or. Rev. Stat. Ann. §646.608(1)(e));

(b) "[r]epresent[ing] that real estate, goods or services are of a particular standard, quality, or grade, or that real estate or goods are of a particular style or model, if the real estate, goods or services are of another" (Or. Rev. Stat. Ann. §646.608(1)(g));

(c) "[a]dvertis[ing] real estate, goods or services with intent not to provide the real estate, goods or services as advertised" (Or. Rev. Stat. Ann. §646.608(1)(i)); and

(d) "[e]ngag[ing] in any other unfair or deceptive conduct in trade or commerce" (Or. Rev. Stat. Ann. §646.608(1)(u)).

4469. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Oregon UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4470. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Oregon UTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

4471. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4472. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4473. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4474. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4475. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Oregon UTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made

misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4476. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Oregon UTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4477. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4478. As a result of Defendants' violations of the Oregon UTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Oregon UTPA.

COUNT 229
Strict Products Liability/Failure to Warn
(Or. Rev. Stat. Ann. §30.920)
(Against All Defendants)

4479. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4480. This cause of action is brought on behalf of the Oregon Class (for the purpose of this section, "Class") against all Defendants.

4481. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4482. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4483. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4484. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4485. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4486. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4487. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4488. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4489. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4490. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4491. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4492. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4493. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4494. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4495. 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.

4496. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4497. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4498. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4499. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4500. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4501. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4502. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 230
Strict Products Liability/Manufacturing Defect
(Or. Rev. Stat. Ann. §30.920)
(Against All Defendants)

4503. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4504. This cause of action is brought on behalf of the Oregon Class (for the purpose of this section, "Class") against all Defendants.

4505. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4506. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4507. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4508. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4509. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4510. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4511. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4512. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4513. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4514. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4515. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4516. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 231
Strict Products Liability/Design Defect
(Or. Rev. Stat. Ann. §30.920)
(Against All Defendants)

4517. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4518. This cause of action is brought on behalf of the Oregon Purchaser Class and the Oregon User Class (for the purpose of this section, "Class") against all Defendants.

4519. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4520. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4521. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4522. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4523. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4524. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4525. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4526. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4527. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4528. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4529. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4530. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4531. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4532. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4533. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4534. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4535. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4536. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

39. Causes of Action Brought on Behalf of the Pennsylvania Class

COUNT 232
Breach of Express Warranty
(13 Pa. C.S. §2313)
(Against All Defendants)

4537. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4538. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against all Defendants.

4539. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of 13 Pa. C.S. §2313 and "sellers" of Ranitidine-Containing Products within the meaning of 13 Pa. C.S. §2313.

4540. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of 13 Pa. C.S. §2313.

4541. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4542. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4543. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4544. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4545. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4546. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4547. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 233
Breach of Implied Warranty
(13 Pa. C.S. §2314)
(Against All Defendants)

4548. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4549. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against all Defendants.

4550. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4551. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. 13 Pa. C.S. §2314.

4552. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4553. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4554. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4555. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4556. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4557. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 234
Violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law
(73 Pa. C.S. §201-1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4558. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4559. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4560. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of 73 Pa. C.S. §201-2(2).

4561. Plaintiffs and Class members purchased the Ranitidine-Containing Products "primarily for personal, family or household purposes" within the meaning of 73 Pa. C.S. §201-9.2(a).

4562. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of 73 Pa. C.S. §201-2(3).

4563. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania CPL") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." 73 Pa. C.S. §201-3.

4564. The Pennsylvania CPL makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have" (73 Pa. C.S. §201-2(4)(v));

(b) "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another" (73 Pa. C.S. §201-2(4)(vii));

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (73 Pa. C.S. §201-2(4)(ix)); and

(d) "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding" (73 Pa. C.S. §201-2(4)(xxi)).

4565. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Pennsylvania CPL by knowingly and intentionally

misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4566. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Pennsylvania CPL, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

4567. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4568. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4569. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4570. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4571. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Pennsylvania CPL in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4572. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Pennsylvania CPL because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products,

including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4573. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4574. As a result of Defendants' violations of the Pennsylvania CPL, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Pennsylvania CPL.

COUNT 235
Strict Products Liability/Failure to Warn

4575. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4576. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against all Defendants.

4577. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they

do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4578. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4579. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4580. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4581. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4582. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4583. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4584. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4585. At all relevant times, the failure to provide these adequate warnings and/or instructions made the Defendants' Ranitidine Containing Products unreasonably dangerous.

4586. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used

as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4587. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4588. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4589. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4590. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4591. 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.

4592. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class 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-Containing Products; continued to aggressively promote the efficacy of their 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-Containing Products.

4593. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

4594. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4595. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4596. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4597. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4598. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 236
Strict Products Liability/Manufacturing Defect

4599. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4600. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against all Defendants.

4601. At all times herein mentioned, the Manufacturer Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4602. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by the Manufacturer Defendants.

4603. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4604. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by the Manufacturer Defendants.

4605. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that the Manufacturer Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4606. The Manufacturer Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4607. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4608. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the

utility of the Ranitidine-Containing Products because of the Manufacturer Defendants' manufacturing defects, which included but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products;

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4609. The manufacturing defects in the Manufacturer Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4610. As a direct and proximate result of the Manufacturing Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4611. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4612. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 237
Strict Products Liability/Design Defect

4613. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4614. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against all Defendants.

4615. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of these Defendants. At all relevant times, the Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4616. At all relevant times, the Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4617. At all relevant times, these Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by the Defendants. At all relevant times, these Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a

consumer market. These Defendants were at all relevant times involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4618. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4619. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4620. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4621. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4622. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4623. Plaintiffs and the Class members used and/or were exposed to the Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4624. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of the Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4625. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4626. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4627. The harm caused by the Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. The Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and these Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4628. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the Defendants' Ranitidine-Containing Products. For example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4629. The defects in the Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4630. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4631. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4632. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 238
Medical Monitoring
(Against All Defendants)

4633. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4634. This cause of action is brought on behalf of the Pennsylvania Class (for the purpose of this section, "Class") against all Defendants.

4635. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

4636. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning,

sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

4637. Defendants breached these duties by, *inter alia,* failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

4638. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA

when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

4639. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

4640. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

4641. Plaintiffs and members of the Class 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.

4642. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

4643. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

4644. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

4645. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

4646. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

4647. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

4648. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

4649. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

4650. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

40. Causes of Action Brought on Behalf of the Puerto Rico Class

COUNT 239
Breach of Express Warranty
(P.R. Laws. Ann. Tit. 31, §3841, *et seq*.)
(Against All Defendants)

4651. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4652. This cause of action is brought on behalf of the Puerto Rico Class (for the purpose of this section, "Class") against all Defendants.

4653. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of P.R. Laws. Ann. Tit. 31, §3841, *et seq*. and "sellers" of Ranitidine-Containing Products within the meaning of P.R. Laws. Ann. Tit. 31, §3841, *et seq*.

4654. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of P.R. Laws. Ann. Tit. 31, §3841, *et seq*.

4655. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or

promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4656. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4657. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4658. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and

> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4659. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4660. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4661. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 240
Breach of Implied Warranty
(P.R. Laws. Ann. Tit. 31, §3841, *et seq*.)
(Against All Defendants)

4662. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4663. This cause of action is brought on behalf of the Puerto Rico Class (for the purpose of this section, "Class") against all Defendants.

4664. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4665. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. P.R. Laws. Ann. Tit. 31, §3841, *et seq*.

4666. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4667. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4668. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4669. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4670. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4671. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 241
Strict Products Liability/Failure to Warn
(Against All Defendants)

4672. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4673. This cause of action is brought on behalf of the Puerto Rico Class (for the purpose of this section, "Class") against all Defendants.

4674. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4675. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4676. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4677. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4678. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4679. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4680. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4681. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4682. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4683. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4684. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4685. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4686. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4687. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4688. 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.

4689. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4690. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4691. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4692. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4693. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

COUNT 242
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

4694. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4695. This cause of action is brought on behalf of the Puerto Rico Class (for the purpose of this section, "Class") against all Defendants.

4696. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4697. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4698. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4699. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4700. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4701. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4702. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved

Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4703. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4704. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4705. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

COUNT 243
Strict Products Liability/Design Defect
(Against All Defendants)

4706. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4707. This cause of action is brought on behalf of the Puerto Rico Class (for the purpose of this section, "Class") against all Defendants.

4708. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4709. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4710. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4711. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4712. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4713. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4714. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4715. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing

Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4716. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4717. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4718. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4719. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4720. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4721. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4722. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4723. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

41. Causes of Action Brought on Behalf of the Rhode Island Class

COUNT 244
Breach of Express Warranty
(R.I. Gen. Laws Ann. §6A-2-313)
(Against All Defendants)

4724. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4725. This cause of action is brought on behalf of the Rhode Island Class (for the purpose of this section, "Class") against all Defendants.

4726. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of R.I. Gen. Laws Ann. §6A-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of R.I. Gen. Laws Ann. §6A-2-313.

4727. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of R.I. Gen. Laws Ann. §6A-2-313.

4728. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4729. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4730. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4731. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4732. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4733. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4734. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 245
Breach of Implied Warranty
(R.I. Gen. Laws Ann. §6A-2-314)
(Against All Defendants)

4735. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4736. This cause of action is brought on behalf of the Rhode Island Class (for the purpose of this section, "Class") against all Defendants.

4737. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4738. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. R.I. Gen. Laws Ann. §6A-2-314.

4739. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4740. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4741. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4742. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4743. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4744. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 246
Strict Products Liability/Failure to Warn
(Against All Defendants)

4745. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4746. This cause of action is brought on behalf of the Rhode Island Class (for the purpose of this section, "Class") against all Defendants.

4747. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4748. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4749. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4750. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4751. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4752. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4753. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4754. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products.

Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4755. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4756. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4757. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4758. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4759. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4760. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4761. 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.

4762. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4763. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4764. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products,

Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4765. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4766. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4767. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4768. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 247
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

4769. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4770. This cause of action is brought on behalf of the Rhode Island Class (for the purpose of this section, "Class") against all Defendants.

4771. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4772. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4773. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4774. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4775. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4776. Manufacturer Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4777. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved

Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4778. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4779. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4780. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4781. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage,

subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4782. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 248
Strict Products Liability/Design Defect
(Against All Defendants)

4783. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4784. This cause of action is brought on behalf of the Rhode Island Class (for the purpose of this section, "Class") against all Defendants.

4785. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4786. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4787. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4788. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4789. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4790. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4791. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4792. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4793. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4794. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4795. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4796. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4797. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4798. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants'

Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4799. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4800. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4801. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4802. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

42. Causes of Action Brought on Behalf of the South Carolina Class

COUNT 249
Breach of Express Warranty
(S.C. Code Ann. §36-2-313)
(Against All Defendants)

4803. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4804. This cause of action is brought on behalf of the South Carolina Class (for the purpose of this section, "Class") against all Defendants.

4805. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of S.C. Code Ann. §36-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of S.C. Code Ann. §36-2-313.

4806. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of S.C. Code Ann. §36-2-313.

4807. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4808. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4809. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4810. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4811. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4812. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4813. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 250
Breach of Implied Warranty
(S.C. Code Ann. §36-2-314)
(Against All Defendants)

4814. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4815. This cause of action is brought on behalf of the South Carolina Class (for the purpose of this section, "Class") against all Defendants.

4816. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4817. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. S.C. Code Ann. §36-2-314.

4818. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4819. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4820. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4821. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4822. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4823. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 251
Violation of the South Carolina Unfair Trade Practices Act
(S.C. Code Ann. §39-5-10, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4824. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4825. This cause of action is brought on behalf of the South Carolina Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4826. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of S.C. Code Ann. §39-5-10(a).

4827. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of S.C. Code Ann. §39-5-10(b).

4828. The South Carolina Unfair Trade Practices Act ("South Carolina UTPA") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." S.C. Code Ann. §39-5-20(a).

4829. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the South Carolina UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4830. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the South Carolina UTPA.

4831. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4832. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class

members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4833. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4834. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4835. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the South Carolina UTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4836. Plaintiffs and the Class members were aggrieved by Defendants' violations of the South Carolina UTPA because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4837. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4838. As a result of Defendants' violations of the South Carolina UTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the South Carolina UTPA.

COUNT 252
Strict Products Liability/Failure to Warn
(S.C. Code Ann. §15-73-10)
(Against All Defendants)

4839. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4840. This cause of action is brought on behalf of the South Carolina Class (for the purpose of this section, "Class") against all Defendants.

4841. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4842. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4843. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4844. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4845. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4846. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4847. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4848. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4849. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4850. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4851. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4852. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4853. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4854. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4855. 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.

4856. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4857. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4858. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4859. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4860. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4861. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4862. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 253
Strict Products Liability/Manufacturing Defect
(S.C. Code Ann. §15-73-10)
(Against All Defendants)

4863. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4864. This cause of action is brought on behalf of the South Carolina Class (for the purpose of this section, "Class") against all Defendants.

4865. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4866. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4867. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4868. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4869. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4870. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4871. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4872. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4873. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4874. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4875. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4876. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 254
Strict Products Liability/Design Defect
(S.C. Code Ann. §15-73-10)
(Against All Defendants)

4877. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4878. This cause of action is brought on behalf of the South Carolina Class (for the purpose of this section, "Class") against all Defendants.

4879. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4880. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4881. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products,

including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4882. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4883. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4884. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4885. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4886. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4887. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4888. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4889. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4890. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4891. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4892. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid

(Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4893. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4894. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4895. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4896. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

43. Causes of Action Brought on Behalf of the South Dakota Class

COUNT 255
Breach of Express Warranty
(S.D. Codified Law §57A-2-313)
(Against All Defendants)

4897. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4898. This cause of action is brought on behalf of the South Dakota Class (for the purpose of this section, "Class") against all Defendants.

4899. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of S.D. Codified Law §57A-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of S.D. Codified Law §57A-2-313.

4900. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of S.D. Codified Law §57A-2-313.

4901. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4902. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4903. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

4904. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

4905. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

4906. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

4907. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

4908. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 256
Breach of Implied Warranty
(S.D. Codified Law §57A-2-314)
(Against All Defendants)

4909. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4910. This cause of action is brought on behalf of the South Dakota Class (for the purpose of this section, "Class") against all Defendants.

4911. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

4912. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. S.D. Codified Law §57A-2-314.

4913. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

4914. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

4915. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

4916. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

4917. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

4918. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 257
Violation of the South Dakota Deceptive Trade Practices and Consumer Protection Law
(S.D. Codified Law §37-24-6, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

4919. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4920. This cause of action is brought on behalf of the South Dakota Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

4921. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of S.D. Codified Law §37-24-1(8).

4922. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of S.D. Codified Law §37-24-1(7).

4923. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of S.D. Codified Law §37-24-1(13).

4924. The South Dakota Deceptive Trade Practices and Consumer Protection Law ("South Dakota CPA") prohibits "deceptive act[s] or practice[s,]" which are defined to include "[k]knowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentations or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise, regardless of whether any person has in fact been misled, deceived, or damaged thereby." S.D. Codified Law §37-24-6(1).

4925. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the South Dakota CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

4926. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the South Dakota CPA.

4927. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

4928. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

4929. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

4930. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

4931. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the South Dakota CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

4932. Plaintiffs and the Class members were aggrieved by Defendants' violations of the South Dakota CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and

failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

4933. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

4934. As a result of Defendants' violations of the South Dakota CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the South Dakota CPA.

COUNT 258
Strict Products Liability/Failure to Warn
(Against All Defendants)

4935. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4936. This cause of action is brought on behalf of the South Dakota Class (for the purpose of this section, "Class") against all Defendants.

4937. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of

Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

4938. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

4939. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

4940. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

4941. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

4942. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

4943. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

4944. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

4945. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

4946. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used

as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

4947. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

4948. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

4949. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

4950. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

4951. 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.

4952. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

4953. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

4954. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

4955. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

4956. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4957. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4958. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 259
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

4959. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4960. This cause of action is brought on behalf of the South Dakota Class (for the purpose of this section, "Class") against all Defendants.

4961. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

4962. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

4963. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4964. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

4965. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

4966. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

4967. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

4968. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the

utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

4969. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

4970. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4971. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4972. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 260
Strict Products Liability/Design Defect
(Against All Defendants)

4973. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4974. This cause of action is brought on behalf of the South Dakota Class (for the purpose of this section, "Class") against all Defendants.

4975. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

4976. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

4977. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

4978. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

4979. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

4980. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

4981. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

4982. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

4983. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

4984. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

4985. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

4986. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

4987. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

4988. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

4989. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

4990. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

4991. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

4992. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

44. Causes of Action Brought on Behalf of the Tennessee Class

COUNT 261
Breach of Express Warranty
(Tenn. Code Ann. §47-2-313)
(Against All Defendants)

4993. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

4994. This cause of action is brought on behalf of the Tennessee Class (for the purpose of this section, "Class") against all Defendants.

4995. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Tenn. Code Ann. §47-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Tenn. Code Ann. §47-2-313.

4996. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Tenn. Code Ann. §47-2-313.

4997. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

4998. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

4999. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5000. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5001. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5002. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5003. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 262
Breach of Implied Warranty
(Tenn. Code Ann. §47-2-314)
(Against All Defendants)

5004. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5005. This cause of action is brought on behalf of the Tennessee Class (for the purpose of this section, "Class") against all Defendants.

5006. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

5007. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Tenn. Code Ann. §47-2-314.

5008. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5009. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5010. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5011. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5012. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5013. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 263
Violation of the Tennessee Consumer Protection Act of 1977
(Tenn. Code Ann. §47-18-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5014. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5015. This cause of action is brought on behalf of the Tennessee Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5016. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Tenn. Code Ann. §47-18-103(14).

5017. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Tenn. Code Ann. §47-18-103(3).

5018. The Ranitidine-Containing Products are "[g]oods" within the meaning of Tenn. Code Ann. §47-18-103(8).

5019. Defendants were and are engaged in "[t]rade" or "commerce" or "consumer transaction[s]" within the meaning of Tenn. Code Ann. §47-18-103(20).

5020. The Tennessee Consumer Protection Act of 1977 ("Tennessee CPA") prohibits "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. §47-18-104(a).

5021. The Tennessee CPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Tenn. Code Ann. §47-18-104(b)(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another" (Tenn. Code Ann. §47-18-104(b)(7)); and

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Tenn. Code Ann. §47-18-104(b)(9)).

5022. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Tennessee CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5023. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Tennessee CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not; and

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised.

5024. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5025. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5026. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5027. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5028. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Tennessee CPA in the course of their business.

Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5029. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Tennessee CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5030. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5031. As a result of Defendants' violations of the Tennessee CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Tennessee CPA.

COUNT 264
Products Liability/Failure to Warn
Tennessee Products Liability Act of 1978
(Against All Defendants)

5032. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5033. This cause of action is brought on behalf of the Tennessee Class (for the purpose of this section, "Class") against all Defendants.

5034. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5035. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5036. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5037. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5038. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5039. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5040. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5041. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5042. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5043. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5044. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

5045. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5046. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5047. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5048. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5049. 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.

5050. Additionally, Defendants further breached their duty of to warn of Ranitidine-Containing Products' risks because they labeled Ranitidine-Containing Products in a false and misleading manner that omitted any mention of the drugs' propensity to expose users to NDMA and failed to suggest or recommend a manner of using Ranitidine-Containing Products so that they are not dangerous to consumers' health when used as labeled and directed, thereby manufacturing, repackaging, offering for sale, delivering, and/or holding misbranded drugs in violation of 21 U.S.C. §§331, 352(a)(1), (j) and Tenn. Code Ann. §§53-1-103(a)(1) & 53-1-109(a)(1),(10).

5051. Defendants' duties as set forth in the above-mentioned statutes parallel their state common-law duty to exercise reasonable care in the warning and labeling of Ranitidine-Containing Products.

5052. The Tennessee and United States legislatures designed the above-mentioned statutes to bolster consumer protection against dangerous pharmaceutical products and to supplement common-law liability for manufacturers of defectively designed and misbranded drugs.

5053. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in Tennessee, are within the specific class of persons that the above-mentioned statutes were designed to protect.

5054. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

5055. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly labeled Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

5056. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known

of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5057. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5058. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5059. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5060. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5061. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage,

subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5062. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5063. Plaintiffs and Class members seek to recover reasonable compensatory damages in an amount to be determined by a jury at trial.

COUNT 265
Products Liability/Manufacturing Defect
Tennessee Products Liability Act of 1978
(Against All Defendants)

5064. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5065. This cause of action is brought on behalf of the Tennessee Class (for the purpose of this section, "Class") against all Defendants.

5066. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5067. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

5068. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5069. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5070. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5071. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5072. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5073. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

5074. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5075. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and

treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5076. Defendants further breached their duty of reasonable care and manufactured Ranitidine-Containing Products in an unreasonably dangerous condition, in that while representing carcinogenic Ranitidine-Containing Products as safe, Defendants failed to employ manufacturing methods to assure Ranitidine-Containing Products met the quality and purity characteristics they purported to possess, thereby manufacturing, repackaging, offering for sale, selling, delivering, and/or holding adulterated drugs in violation of 21 U.S.C. §§331, & 351(a)(2)(B) and Tenn. Code Ann. §53-1-103(a)(1).

5077. Defendants' duties as specified in the above-mentioned statutes parallel their common-law duty to exercise reasonable care in manufacturing Ranitidine-Containing Products.

5078. The Tennessee and United States legislatures designed the above-mentioned statutes to protect pharmaceutical consumers by bolstering consumer protection against dangerous pharmaceutical products and supplementing common-law liability for manufacturers of adulterated drugs.

5079. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in Tennessee, are within the specific class of persons that the above-mentioned statutes were designed to protect.

5080. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

5081. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly manufactured and defective Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

5082. Additionally, Manufacturer Defendants breached their duty to manufacture a safe product by failing to follow cGMPs in the storing, handling, and warehousing of Ranitidine-Containing Products, thereby increasing the risk that the drugs would produce NDMA during storage and/or transport, in that Defendants failed to ensure that Ranitidine-Containing Products were stored, handled, and warehoused under appropriate conditions of temperature, humidity, and light so that their identity, strength, quality, and purity was not adversely affected, in violation of the cGMPs set forth in 21 C.F.R. §211.142(b).

5083. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5084. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5085. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5086. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5087. Plaintiffs and Class members seek to recover reasonable compensatory damages in an amount to be determined by a jury at trial.

COUNT 266
Products Liability/Design Defect
Tennessee Products Liability Act of 197
(Against All Defendants)

5088. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5089. This cause of action is brought on behalf of the Tennessee Class (for the purpose of this section, "Class") against all Defendants.

5090. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5091. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing, designing, and labeling Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

5092. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5093. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5094. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5095. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous

to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5096. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

5097. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5098. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5099. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5100. Defendants further breached their duty of care and designed a defective product because they labeled Ranitidine-Containing Products in a false and misleading manner that omitted any mention of the drugs' propensity to expose users to NDMA and failed to suggest or recommend a manner of using Ranitidine-Containing Products so that they are not dangerous to consumers' health when used as labeled and directed, thereby manufacturing, repackaging, offering for sale, delivering, and/or holding misbranded drugs in violation of 21 U.S.C. §§331, 352(a)(1), (j) and Tenn. Code Ann. §§53-1-103(a)(1) & 53-1-109(a)(1),(10).

5101. Defendants' duties as set forth in the above-mentioned statutes parallel their state common-law duty to exercise reasonable care in the designing and labeling of Ranitidine-Containing Products.

5102. The Tennessee and United States legislatures designed the above-mentioned statutes to bolster consumer protection against dangerous pharmaceutical products and to supplement common-law liability for manufacturers of defectively designed and misbranded drugs.

5103. Plaintiffs and Class members, as purchasers and consumers of Ranitidine-Containing Products in Tennessee, are within the specific class of persons that the above-mentioned statutes were designed to protect.

5104. The harm that Plaintiffs and Class members suffered – namely, unknowingly purchasing and consuming dangerous substances when using Ranitidine-Containing Products as recommended – is that which the above-statutes contemplate and were designed to prevent.

5105. Defendants' violations of the above-mentioned statutes were a direct and proximate cause of Plaintiffs' and Class members' purchasing and consuming improperly labeled and designed Ranitidine-Containing Products and the resulting harm therefrom, and constitute negligence per se.

5106. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5107. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5108. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5109. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5110. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5111. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5112. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5113. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5114. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5115. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

5116. Plaintiffs and Class members seek to recover reasonable compensatory damages in an amount to be determined by a jury at trial.

45. Causes of Action Brought on Behalf of the Texas Class

COUNT 267
Breach of Express Warranty
(Tex. Bus. & Com. Code Ann. §2.313)
(Against All Defendants)

5117. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5118. This cause of action is brought on behalf of the Texas Class (for the purpose of this section, "Class") against all Defendants.

5119. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Tex. Bus. & Com. Code Ann. §2.313 and "sellers" of Ranitidine-Containing Products within the meaning of Tex. Bus. & Com. Code Ann. §2.313.

5120. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Tex. Bus. & Com. Code Ann. §2.313.

5121. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5122. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5123. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5124. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class

members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

5125. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5126. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5127. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5128. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 268
Breach of Implied Warranty
(Tex. Bus. & Com. Code Ann. §2.314)
(Against All Defendants)

5129. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5130. This cause of action is brought on behalf of the Texas Class (for the purpose of this section, "Class") against all Defendants.

5131. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

5132. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Tex. Bus. & Com. Code Ann. §2.314.

5133. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5134. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5135. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5136. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5137. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5138. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 269
Violation of the Texas Deceptive Trade Practices-Consumer Protection Act
(Tex. Bus. & Com. Code Ann. §17.41, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5139. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5140. This cause of action is brought on behalf of the Texas Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5141. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(3).

5142. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(4).

5143. The Ranitidine-Containing Products are "[g]oods" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(1).

5144. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(6).

5145. The Texas Deceptive Trade Practices-Consumer Protection Act ("Texas DTPA") prohibits "[f]alse, misleading, or deceptive acts or practices in the conduct of any trade or commerce," Tex. Bus. & Com. Code Ann. §17.46(a), and an "[u]nconscionable action or course of action," which means "an act or practice which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree." Tex. Bus. & Com. Code Ann. §§17.45(5) and 17.50(a)(3).

5146. The Texas DTPA makes unlawful specific acts, including:

(a) "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Tex. Bus. & Com. Code Ann. §17.46(5));

(b) "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Tex. Bus. & Com. Code Ann. §17.46(7)); and

(c) "advertising goods or services with intent not to sell them as advertised" (Tex. Bus. & Com. Code Ann. §17.46(9)).

5147. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Texas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5148. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Texas DTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not; and

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised.

5149. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5150. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5151. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5152. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5153. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Texas DTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5154. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Texas DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended

purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class Members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5155. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5156. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Tex. Bus. & Com. Code Ann. §17.505(a) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

5157. As a result of Defendants' violations of the Texas DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Texas DTPA.

COUNT 270
Products Liability/Failure to Warn
(Against All Defendants)

5158. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5159. This cause of action is brought on behalf of the Texas Class (for the purpose of this section, "Class") against all Defendants.

5160. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5161. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5162. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5163. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5164. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5165. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5166. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5167. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5168. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5169. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5170. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5171. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5172. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5173. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5174. 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.

5175. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5176. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5177. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5178. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5179. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5180. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5181. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 271
Products Liability/Manufacturing Defect
(Against All Defendants)

5182. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5183. This cause of action is brought on behalf of the Texas Class (for the purpose of this section, "Class") against all Defendants.

5184. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5185. At all relevant times, Defendants had a continuing duty to exercise reasonable care in manufacturing Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

5186. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5187. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5188. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5189. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design,

manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5190. Manufacturer Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5191. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5192. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5193. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be manufactured by a reasonably prudent manufacturer or seller exercising reasonable and due care.

5194. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5195. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5196. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5197. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 272
Products Liability/Design Defect
(Against All Defendants)

5198. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5199. This cause of action is brought on behalf of the Texas Class (for the purpose of this section, "Class") against all Defendants.

5200. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5201. At all relevant times, Defendants had a duty to exercise reasonable care in manufacturing, designing, and labeling Ranitidine-Containing Products to prevent harm to foreseeable users and consumers, including Plaintiffs and Class members.

5202. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5203. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5204. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5205. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5206. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5207. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5208. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5209. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5210. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5211. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5212. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5213. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5214. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5215. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller exercising reasonable and due care.

5216. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5217. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5218. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5219. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

46. Causes of Action Brought on Behalf of the Utah Class

COUNT 273
Breach of Express Warranty
(Utah Code Ann. §70A-2-313)
(Against All Defendants)

5220. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5221. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against all Defendants.

5222. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Utah Code Ann. §70A-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Utah Code Ann. §70A-2-313.

5223. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Utah Code Ann. §70A-2-313.

5224. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5225. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5226. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5227. The express warranties Defendants created with respect to Ranitidine-Containing Products were material to reasonable consumers, including Plaintiffs and the Class members, who were intended beneficiaries of Defendants' express warranties and who justifiably relied on Defendants' express warranties in connection with their decision to purchase Ranitidine-Containing Products. Specifically, Plaintiffs and the Class members detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Ranitidine-Containing Products in deciding to purchase the product. Plaintiffs and the Class

members reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Ranitidine-Containing Products. Plaintiffs and the Class members would not have purchased or used Ranitidine-Containing Products had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

5228. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5229. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5230. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5231. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 274
Breach of Implied Warranty
(Utah Code Ann. §70A-2-314)
(Against All Defendants)

5232. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5233. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against all Defendants.

5234. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiff and member of the Class and were in the business of selling such products.

5235. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Utah Code Ann. §70A-2-314.

5236. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5237. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5238. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5239. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5240. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5241. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 275
Violation of the Utah Consumer Sales Practices Act
(Utah. Code Ann. §13-11-1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5242. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5243. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5244. Defendants are "[s]upplier[s]" within the meaning of Utah Code Ann. §13-11-3(6).

5245. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Utah Code Ann. §13-11-3(5).

5246. Defendants were and are engaged in "consumer transactions" within the meaning of Utah Code Ann. §13-11-3(2)(a).

5247. The Utah Consumer Sales Practices Act ("Utah CSPA") prohibits any "deceptive act or practice by a supplier in connection with a consumer transaction." Utah Code Ann. §13-11-4(1). "An unconscionable act or practice by a supplier in connection with a consumer transaction" also violates the Utah CSPA. Utah Code Ann. §13-11-5(1).

5248. The Utah CSPA makes unlawful specific acts, including:

(a) "indicat[ing] that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits, if it has not" (Utah Code Ann. §13-11-4(2)(a)); and

(b) "indicat[ing] that the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not" (Utah Code Ann. §13-11-4(2)(b)).

5249. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Utah CSPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5250. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Utah CSPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have; and

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not.

5251. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5252. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5253. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5254. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5255. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Utah CSPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5256. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Utah CSPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have

purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5257. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5258. As a result of Defendants' violations of the Utah CSPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Utah CSPA.

COUNT 276
Violation of the Utah Truth in Advertising Law
(Utah Code Ann. §13-11a-1, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5259. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5260. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5261. Defendants are "[s]uppliers" within the meaning of Utah Code Ann. §13-11a-2(17).

5262. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Utah Code Ann. §13-11a-2(7).

5263. The Ranitidine-Containing Products are "goods" within the meaning of Utah Code Ann. §13-11a-2(4).

5264. The Utah Truth in Advertising Law ("Utah TAL") prohibits any deceptive practice undertaken "in the course of a person's business." Utah Code Ann. §13-11a-3(1).

5265. The Utah TAL makes unlawful specific acts, including:

(a) "represent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have" (Utah Code Ann. §13-11a-3(1)(e));

(b) "represent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Utah Code Ann. §13-11a-3(1)(g));

(c) "advertis[ing] goods or services with intent not to sell them as advertised" (Utah Code Ann. §13-11a-3(1)(i)); and

(d) "engag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding" (Utah Code Ann. §13-11a-3(1)(t)).

5266. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Utah TAL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5267. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Utah TAL, including:

(a) representing that Ranitidine-Containing Products were both safe and effective for the lifetime of the product, when in fact, they were not;

(b) representing that consumption of Ranitidine-Containing Products had characteristics, ingredients, uses, benefits, or qualities that they do not have;

(c) representing that Ranitidine-Containing Products are of a particular standard, quality, or grade when they are not;

(d) advertising Ranitidine-Containing Products with the intent not to sell them as advertised; and

(e) engaging in any other conduct that creates a likelihood of confusion.

5268. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5269. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5270. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5271. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5272. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had

concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5273. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Utah TAL in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5274. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Utah TAL because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5275. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5276. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

5277. As a result of Defendants' violations of the Utah TAL, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Utah TAL.

COUNT 277
Strict Products Liability/Failure to Warn
(Against All Defendants)

5278. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5279. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against all Defendants.

5280. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and

unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5281. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5282. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5283. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5284. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they

knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5285. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5286. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5287. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5288. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5289. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5290. The product was dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of that product in that community considering the product's characteristics, propensities, risks, dangers, and uses together with any actual knowledge, training, or experience possessed by that particular buyer, user, or consumer, including any healthcare provider.

5291. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5292. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5293. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5294. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5295. 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.

5296. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5297. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5298. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5299. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5300. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5301. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5302. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 278
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

5303. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5304. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against all Defendants.

5305. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5306. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5307. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5308. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5309. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5310. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5311. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved

Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5312. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5313. The product was dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of that product in that community considering the product's characteristics, propensities, risks, dangers, and uses together with any actual knowledge, training, or experience possessed by that particular buyer, user, or consumer, including any healthcare provider.

5314. The methods and techniques of manufacturing, inspecting and testing the product were not in conformity with government standards established for the pharmaceutical industry which were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were adopted.

5315. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5316. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5317. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5318. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 279
Strict Products Liability/Design Defect

5319. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5320. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against all Defendants.

5321. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream

of commerce. These actions were under the ultimate control and supervision of these Defendants. At all relevant times, the Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5322. At all relevant times, the Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5323. At all relevant times, these Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by the Defendants. At all relevant times, these Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. These Defendants were at all relevant times involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5324. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5325. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5326. The Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by these Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5327. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5328. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5329. Plaintiffs and the Class members used and/or were exposed to the Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5330. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of the Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5331. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5332. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5333. The harm caused by the Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. The Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and these Defendants could have

designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5334. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the Defendants' Ranitidine-Containing Products. For example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5335. The defects in the Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5336. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5337. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5338. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 280
Medical Monitoring
(Against All Defendants)

5339. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5340. This cause of action is brought on behalf of the Utah Class (for the purpose of this section, "Class") against all Defendants.

5341. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

5342. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

5343. Defendants breached these duties by, *inter alia*, failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to

know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

5344. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

5345. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

5346. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

5347. Plaintiffs and members of the Class 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.

5348. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

5349. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

5350. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5351. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

5352. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

5353. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5354. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5355. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5356. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

47. Causes of Action Brought on Behalf of the Vermont Class

COUNT 281
Breach of Express Warranty
(Vt. Stat. Ann. tit. 9A §2-313)
(Against All Defendants)

5357. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5358. This cause of action is brought on behalf of the Vermont Class (for the purpose of this section, "Class") against all Defendants.

5359. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Vt. Stat. Ann. tit. 9A §2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Vt. Stat. Ann. tit. 9A §2-313.

5360. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Vt. Stat. Ann. tit. 9A §2-313.

5361. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5362. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5363. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5364. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the

Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5365. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5366. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5367. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 282
Breach of Implied Warranty
(Vt. Stat. Ann. tit. 9A §2-314)
(Against All Defendants)

5368. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5369. This cause of action is brought on behalf of the Vermont Class (for the purpose of this section, "Class") against all Defendants.

5370. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

5371. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Vt. Stat. Ann. tit. 9A §2-314.

5372. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5373. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5374. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5375. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5376. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5377. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 283
Violation of the Vermont Consumer Fraud Act
(Vt. Stat. Ann. tit. 9, §2451, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5378. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5379. This cause of action is brought on behalf of the Vermont Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5380. Defendants are "[s]eller[s]" within the meaning of Vt. Stat. Ann. tit. 9, §2451a(c).

5381. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Vt. Stat. Ann. tit. 9, §2451a(a).

5382. The Ranitidine-Containing Products are "[g]oods" within the meaning of Vt. Stat. Ann. tit. 9, §2451a(b).

5383. The Vermont consumer fraud act ("Vermont CFA") prohibits "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce." Vt. Stat. Ann. tit. 9, §2453(a).

5384. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Vermont CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5385. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Vermont CFA.

5386. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5387. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were

likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5388. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5389. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5390. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Vermont CFA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5391. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Vermont CFA because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5392. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5393. As a result of Defendants' violations of the Vermont CFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Vermont CFA.

COUNT 284
Strict Products Liability/Failure to Warn
(Against All Defendants)

5394. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5395. This cause of action is brought on behalf of the Vermont Class (for the purpose of this section, "Class") against all Defendants.

5396. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5397. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5398. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5399. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5400. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5401. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5402. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5403. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5404. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5405. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5406. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5407. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5408. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5409. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5410. 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.

5411. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5412. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5413. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5414. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5415. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5416. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5417. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 285
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

5418. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5419. This cause of action is brought on behalf of the Vermont Class (for the purpose of this section, "Class") against all Defendants.

5420. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5421. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5422. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5423. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5424. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5425. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5426. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5427. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5428. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5429. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5430. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5431. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 286
Strict Products Liability/Design Defect
(Against All Defendants)

5432. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5433. This cause of action is brought on behalf of the Vermont Class (for the purpose of this section, "Class") against all Defendants.

5434. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5435. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5436. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products,

including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5437. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5438. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5439. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5440. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5441. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5442. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5443. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5444. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5445. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5446. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5447. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid

(Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5448. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5449. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5450. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5451. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

48. Causes of Action Brought on Behalf of the Virginia Class

COUNT 287
Breach of Express Warranty
(Va. Code Ann. §8.2-313)
(Against All Defendants)

5452. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5453. This cause of action is brought on behalf of the Virginia Class (for the purpose of this section, "Class") against all Defendants.

5454. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Va. Code Ann. §8.2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Va. Code Ann. §8.2-313.

5455. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Va. Code Ann. §8.2-313.

5456. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5457. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5458. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5459. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the

Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5460. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5461. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5462. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 288
Breach of Implied Warranty
(Va. Code Ann. §8.2-314)
(Against All Defendants)

5463. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5464. This cause of action is brought on behalf of the Virginia Class (for the purpose of this section, "Class") against all Defendants.

5465. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiff and member of the Class and were in the business of selling such products.

5466. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Va. Code Ann. §8.2-314.

5467. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5468. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5469. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5470. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5471. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5472. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 289
Violation of the Virginia Consumer Protection Act
(Va. Code Ann. §59.1-196, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5473. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5474. This cause of action is brought on behalf of the Virginia Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5475. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Va. Code Ann. §59.1-198.

5476. Defendants were and are "[s]upplier[s]" within the meaning of Va. Code Ann. §59.1-198.

5477. The Ranitidine-Containing Products are "[g]oods" within the meaning of Va. Code Ann. §59.1-198.

5478. Defendants were and are engaged in "[c]onsumer transaction[s]" within the meaning of Va. Code Ann. §59.1-198.

5479. The Virginia Consumer Protection Act ("Virginia CPA") prohibits "fraudulent acts or practices committed by a supplier in connection with a consumer transaction." Va. Code Ann. §59.1-200(A).

5480. The Virginia CPA makes unlawful specific acts, including:

(a) "[m]isrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits" (Va. Code Ann. §59.1-200(A)(5));

(b) "[m]isrepresenting that goods or services are of a particular standard, quality, grade, style, or model" (Va. Code Ann. §59.1-200(A)(6));

(c) "[a]dvertising goods or services with intent not to sell them as advertised, or with intent not to sell at the price or upon the terms advertised" (Va. Code Ann. §59.1-200(A)(8)); and

(d) "[u]sing any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction" (Va. Code Ann. §59.1-200(A)(14)).

5481. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Virginia CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5482. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Virginia CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

5483. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5484. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5485. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5486. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5487. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Virginia CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5488. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Virginia CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not

engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5489. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5490. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

5491. As a result of Defendants' violations of the Virginia CPA, as alleged herein, Plaintiffs and the Class members seek an order awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Virginia CPA.

49. Causes of Action Brought on Behalf of the Washington Class

COUNT 290
Breach of Express Warranty
(Wash. Rev. Code Ann. §62A 2-313)
(Against All Defendants)

5492. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5493. This cause of action is brought on behalf of the Washington Class (for the purpose of this section, "Class") against all Defendants.

5494. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Wash. Rev. Code Ann. §62A.2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Wash. Rev. Code Ann. §62A.2-313.

5495. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Wash. Rev. Code Ann. §62A.2-313.

5496. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5497. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5498. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5499. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5500. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5501. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5502. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 291
Breach of Implied Warranty
(Wash. Rev. Code Ann. §62A.2-314)
(Against All Defendants)

5503. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5504. This cause of action is brought on behalf of the Washington Class (for the purpose of this section, "Class") against all Defendants.

5505. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiff and member of the Class and were in the business of selling such products.

5506. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Wash. Rev. Code Ann. §62A 2-314.

5507. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5508. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5509. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to

establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5510. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5511. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5512. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 292
Violation of the Washington Consumer Protection Act
(Wash. Rev. Code Ann. §19.86.010, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5513. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5514. This cause of action is brought on behalf of the Washington Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5515. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Wash. Rev. Code Ann. §19.86.010(1).

5516. The Ranitidine-Containing Products are "[a]ssets" within the meaning of Wash. Rev. Code Ann. §19.86.010(3).

5517. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of Wash. Rev. Code Ann. §19.86.010(2).

5518. The Washington Consumer Protection Act ("Washington CPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code Ann. §19.86.020.

5519. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Washington CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5520. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Washington CPA.

5521. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5522. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were

likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5523. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5524. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5525. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Washington CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5526. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Washington CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5527. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5528. As a result of Defendants' violations of the Washington CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Washington CPA.

COUNT 293
Strict Products Liability/Failure to Warn
Washington Product Liability Act
(Against All Defendants)

5529. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5530. This cause of action is brought on behalf of the Washington Class (for the purpose of this section, "Class") against all Defendants.

5531. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5532. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5533. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5534. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5535. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5536. At the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the Defendants inadequate and the Defendants could have provided the warnings or instructions regarding the risk of harm.

5537. A reasonably prudent manufacturer should have learned about a danger connected with the Ranitidine-Containing Products after they were manufactured. Accordingly, Defendants were under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances but failed to exercise reasonable care to inform product users and healthcare providers.

5538. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5539. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their

drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5540. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5541. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5542. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5543. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5544. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5545. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5546. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5547. 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.

5548. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5549. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5550. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5551. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5552. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5553. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5554. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 294
Strict Products Liability/Manufacturing Defect
Washington Product Liability Act
(Against All Defendants)

5555. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5556. This cause of action is brought on behalf of the Washington Class (for the purpose of this section, "Class") against all Defendants.

5557. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5558. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5559. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5560. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5561. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their

manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5562. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5563. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5564. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5565. Accordingly, the product deviated in a material way from the design specifications or performance standards of the Defendants and/or deviated in some material way from otherwise identical units of the same product line.

5566. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5567. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5568. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5569. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 295
Strict Products Liability/Design Defect
Washington Product Liability Act
(Against All Defendants)

5570. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5571. This cause of action is brought on behalf of the Washington Class (for the purpose of this section, "Class") against all Defendants.

5572. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5573. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5574. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5575. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5576. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous, and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5577. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5578. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5579. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing

Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5580. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5581. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5582. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5583. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5584. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5585. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5586. At the time of manufacture, the likelihood that the Ranitidine-Containing Products would cause Plaintiffs' and members' of the class harm or similar harms, and the seriousness of those harms, outweighed the burden on the defendants to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product.

5587. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5588. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5589. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5590. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

50. Causes of Action Brought on Behalf of the West Virginia Class

COUNT 296
Breach of Express Warranty
(W. Va. Code Ann. §46-2-313)
(Against All Defendants)

5591. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5592. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against all Defendants.

5593. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of W. Va. Code Ann. §46-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of W. Va. Code Ann. §46-2-313.

5594. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of W. Va. Code Ann. §46-2-313.

5595. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5596. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5597. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5598. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5599. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5600. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5601. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 297
Breach of Implied Warranty
(W. Va. Code Ann. §46-2-314)
(Against All Defendants)

5602. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5603. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against all Defendants.

5604. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

5605. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. W. Va. Code Ann. §46-2-314.

5606. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5607. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5608. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5609. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5610. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the

Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5611. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 298
Violation of the West Virginia Consumer Credit and Protection Act
(W. Va. Code Ann. §46A-1-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5612. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5613. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5614. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of W. Va. Code Ann. §46A-1-102(31).

5615. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of W. Va. Code Ann. §§46A-1-102(12) and 46A-6-102(2).

5616. The OTC Ranitidine-Containing Products are "[g]oods" within the meaning of W. Va. Code Ann. §46A-1-102(21).

5617. Defendants were and are engaged in "[t]rade" or "commerce" within the meaning of W. Va. Code Ann. §46A-6-102(6).

5618. The West Virginia Consumer Credit and Protection Act ("West Virginia CCPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts of practices in the conduct of any trade or commerce." W. Va. Code Ann. §46A-6-104.

5619. The West Virginia CCPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have" (W. Va. Code Ann. §46A-6-102(7)(E));

(b) "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another" (W. Va. Code Ann. §46A-6-102(7)(G));

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (W. Va. Code Ann. §46A-6-102(7)(I));

(d) "[e]ngaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding" (W. Va. Code Ann. §46A-6-102(7)(L)); and

(e) "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby" (W. Va. Code Ann. §46A-6-102(7)(M)).

5620. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the West Virginia CCPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding OTC Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5621. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding OTC Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended

purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the West Virginia CCPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

5622. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of OTC Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5623. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of OTC Ranitidine-Containing Products.

5624. The facts regarding OTC Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to OTC Ranitidine-Containing Products.

5625. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5626. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the West Virginia CCPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding OTC Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding OTC Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5627. Plaintiffs and the Class members were aggrieved by Defendants' violations of the West Virginia CCPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding OTC Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased OTC Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding OTC Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs

and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5628. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5629. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of OTC Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to W. Va. Code Ann. §46A-6-106(c) to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

5630. As a result of Defendants' violations of the West Virginia CCPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the West Virginia CCPA.

COUNT 299
Strict Products Liability/Failure to Warn
(Against All Defendants)

5631. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5632. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against all Defendants.

5633. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5634. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5635. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5636. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5637. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5638. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5639. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5640. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5641. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5642. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5643. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

5644. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5645. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5646. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5647. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5648. 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.

5649. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5650. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5651. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5652. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5653. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5654. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5655. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 300
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

5656. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5657. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against all Defendants.

5658. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5659. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5660. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5661. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5662. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5663. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5664. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

5665. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5666. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5667. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5668. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5669. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5670. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 301
Strict Products Liability/Design Defect
(Against All Defendants)

5671. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5672. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against all Defendants.

5673. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5674. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5675. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5676. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5677. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5678. The Ranitidine-Containing Products, because of their dangerous condition and Defendants' knowledge of such dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller.

5679. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5680. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5681. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5682. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5683. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5684. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5685. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5686. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5687. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5688. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5689. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5690. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5691. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 302
Medical Monitoring
(Against All Defendants)

5692. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5693. This cause of action is brought on behalf of the West Virginia Class (for the purpose of this section, "Class") against all Defendants.

5694. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially deadly cancers and caused them bodily injury in the form of cellular, sub-cellular, and/or genetic injuries.

5695. At all relevant times Defendants had a duty to, *inter alia*:

(a) exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product;

(b) to provide accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA; and

(c) disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption.

5696. Defendants breached these duties by, *inter alia*, failing to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that consumer use of the products created a significant risk of harm and unreasonably dangerous side effects, including significantly increasing the risk of developing various types of serious and potentially deadly cancers and causing bodily injury in the form of cellular, sub-cellular, and/or genetic injuries; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test Ranitidine-Containing Products because they knew that the chemical posed serious health risks to humans.

5697. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Products are ingested and/or the elevated levels of NDMA that result from the transport and storage of Ranitidine-Containing Products.

5698. Accordingly, at all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that use of Ranitidine-Containing Products could cause or be associated with Plaintiffs' and Class members' injuries, and thus, could create a dangerous and unreasonable risk of injury to the end users of their products, including Plaintiffs and members of the Class.

5699. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that consumers such as Plaintiffs and members of the Class would suffer injuries in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

5700. Plaintiffs and members of the Class 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.

5701. Due to the unsafe levels of NDMA present in Ranitidine-Containing Products, which present an unacceptable and increased risk of causing cancer, the FDA was compelled to order the immediate ban of all Ranitidine-Containing Products on April 1, 2020.

5702. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the Class would not have purchased or consumed the Ranitidine-Containing Products, and therefore would have avoided such injury.

5703. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of various cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

5704. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing various cancers. This

diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, various cancers.

5705. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of cancers.

5706. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5707. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for various cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5708. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5709. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

51. Causes of Action Brought on Behalf of the Wisconsin Class

COUNT 303
Breach of Express Warranty
(Wis. Stat. Ann. §402.313)
(Against All Defendants)

5710. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5711. This cause of action is brought on behalf of the Wisconsin Class (for the purpose of this section, "Class") against all Defendants.

5712. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Wis. Stat. Ann. §402.313 and "sellers" of Ranitidine-Containing Products within the meaning of Wis. Stat. Ann. §402.313.

5713. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Wis. Stat. Ann. §402.313.

5714. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5715. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5716. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5717. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5718. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5719. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5720. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 304
Breach of Implied Warranty
(Wis. Stat. Ann. §402.314)
(Against All Defendants)

5721. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5722. This cause of action is brought on behalf of the Wisconsin Class (for the purpose of this section, "Class") against all Defendants.

5723. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

5724. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Wis. Stat. Ann. §402.314.

5725. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5726. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5727. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5728. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5729. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5730. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 305
Violation of the Wisconsin Deceptive Trade Practices Act
(Wis. Stat. Ann. §100.18, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5731. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5732. This cause of action is brought on behalf of the Wisconsin Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5733. Defendants are "person[s], firm[s], corporation[s] or association[s]" within the meaning of Wis. Stat. Ann. §100.18(1).

5734. Plaintiffs and the Class members are members of "the public" within the meaning of Wis. Stat. Ann. §100.18(1).

5735. The Ranitidine-Containing Products are "merchandise" within the meaning of Wis. Stat. Ann. §100.18(1).

5736. The Wisconsin Deceptive Trade Practices Act ("Wisconsin DTPA") prohibits any "assertion, representation or statement of fact which is untrue, deceptive or misleading." Wis. Stat. Ann. §100.18(1).

5737. Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Wisconsin DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5738. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Wisconsin DTPA.

5739. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5740. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products.

5741. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5742. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5743. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Wisconsin DTPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed

exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5744. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Wisconsin DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5745. Defendants' violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

5746. As a result of Defendants' violations of the Wisconsin DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Wisconsin DTPA.

COUNT 306
Strict Products Liability/Failure to Warn
(Against All Defendants)

5747. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5748. This cause of action is brought on behalf of the Wisconsin Class (for the purpose of this section, "Class") against all Defendants.

5749. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5750. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5751. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous

risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5752. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5753. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5754. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5755. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5756. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or

instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5757. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5758. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5759. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5760. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5761. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5762. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5763. 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.

5764. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5765. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public

service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5766. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5767. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5768. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5769. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5770. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 307
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

5771. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5772. This cause of action is brought on behalf of the Wisconsin Class (for the purpose of this section, "Class") against all Defendants.

5773. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5774. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5775. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5776. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5777. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5778. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5779. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5780. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5781. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5782. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they

otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5783. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5784. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 308
Strict Products Liability/Design Defect
(Against All Defendants)

5785. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5786. This cause of action is brought on behalf of the Wisconsin Class (for the purpose of this section, "Class") against all Defendants.

5787. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested,

assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5788. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5789. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5790. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5791. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5792. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by

Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5793. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5794. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5795. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5796. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5797. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5798. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5799. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing

Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5800. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5801. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5802. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5803. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5804. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

52. Causes of Action Brought on Behalf of the Wyoming Class

COUNT 309
Breach of Express Warranty
(Wyo. Stat. Ann. §34.1-2-313)
(Against All Defendants)

5805. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5806. This cause of action is brought on behalf of the Wyoming Class (for the purpose of this section, "Class") against all Defendants.

5807. Defendants are, and at all relevant times were, "merchants" with respect to Ranitidine-Containing Products within the meaning of Wyo. Stat. Ann. §34.1-2-313 and "sellers" of Ranitidine-Containing Products within the meaning of Wyo. Stat. Ann. §34.1-2-313.

5808. Plaintiffs and the Class members are, and at all relevant times were, "buyers" within the meaning of Wyo. Stat. Ann. §34.1-2-313.

5809. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

5810. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their

purchase or use by Plaintiffs and the Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

5811. Defendants' affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

5812. Despite the express warranties Defendants created with respect to Ranitidine-Containing Products, Defendants delivered Ranitidine-Containing Products to Plaintiffs and the Class members that did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Ranitidine-Containing Products and by expressly limiting the risks associated with use within their warnings and labels; and
>
> Defendants represented that Ranitidine-Containing Products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that Ranitidine-Containing Products, therefore, were not safer than alternatives available on the market.

5813. Defendants had sole access to material facts concerning the nature of the risks associated with their Ranitidine-Containing Products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in Ranitidine-Containing Products' warnings and labels were inadequate and inaccurate.

5814. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members sustained an economic loss in an amount to be proven at trial.

5815. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 310
Breach of Implied Warranty
(Wyo. Stat. Ann. §34.1-2-314)
(Against All Defendants)

5816. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5817. This cause of action is brought on behalf of the Wyoming Class (for the purpose of this section, "Class") against all Defendants.

5818. At all relevant times, Defendants were merchants with respect to Ranitidine-Containing Products which were sold to Plaintiffs and members of the Class and were in the business of selling such products.

5819. Each Ranitidine-Containing Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. Wyo. Stat. Ann. §34.1-2-314.

5820. Defendants breached their implied warranty of merchantability because their products were not in merchantable condition when sold, were defective when sold, did not conform to the promises and affirmations of fact made on the products' containers or labels, and/or do not possess even the most basic degree of fitness for ordinary use, *i.e.*, as consumer medication intended for human consumption.

5821. Defendants' Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended, and their use carries an increased risk of developing severe injuries.

5822. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendants or their agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

5823. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

5824. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendants' breaches of implied warranties of merchantability. Plaintiffs and members of the Class were damaged as a result of Defendants' breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

5825. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 311
Violation of the Wyoming Consumer Protection Act
(Wyo. Stat. Ann. §40-12-101, *et seq.*)
(Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants)

5826. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5827. This cause of action is brought on behalf of the Wyoming Class (for the purpose of this section, "Class") against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants (for the purpose of this section, "Defendants").

5828. Defendants, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Wyo. Stat. Ann. §40-12-102(a)(i).

5829. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Wyo. Stat. Ann. §40-12-102(a)(vi).

5830. Defendants were and are engaged in "[c]onsumer transactions" within the meaning of Wyo. Stat. Ann. §40-12-102(a)(ii). These consumer transactions occurred "in the course of [Defendants'] business" under Wyo. Stat. Ann. §40-12-105(a).

5831. The Wyoming Consumer Protection Act ("Wyoming CPA") prohibits deceptive trade practices knowingly used "in the course of . . . business and in connection with a consumer transaction." Wyo. Stat. Ann. §40-12-105(a).

5832. The Wyoming CPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that merchandise has a source, origin, sponsorship, approval, accessories or uses it does not have" (Wyo. Stat. Ann. §40-12-105(a)(i));

(b) "[r]epresent[ing] that merchandise is of a particular standard, grade, style or model, if it is not" (Wyo. Stat. Ann. §40-12-105(a)(iii));

(c) "[a]dvertis[ing] merchandise with intent not to sell it as advertised" (Wyo. Stat. Ann. §40-12-105(a)(x)); and

(d) "[e]ngag[ing] in unfair or deceptive acts or practices" (Wyo. Stat. Ann. §40-12-105(a)(xv)).

5833. In the course of their business Defendants, directly or through their agents, employees, and/or subsidiaries, violated the Wyoming CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-

Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above.

5834. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Wyoming CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in connection with a consumer transaction.

5835. Defendants' misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

5836. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

5837. Plaintiffs and the Class members were aggrieved by Defendants' violations of the Wyoming CPA because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were inherently defective, unreasonably dangerous, and not fit to be used for their intended purpose. Specifically, Plaintiffs and the Class members purchased Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

5838. Plaintiffs and Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and Class members did not, and could not, unravel Defendants' deception on their own.

5839. Defendants had an ongoing duty to Plaintiffs and the Class members to refrain from unfair and deceptive practices under the Wyoming CPA in the course of their business. Specifically, Defendants owed Plaintiffs and Class members a duty to disclose all the material facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose because they possessed exclusive knowledge, they intentionally concealed the facts regarding Ranitidine-Containing Products, including that such drugs were defective, unreasonably dangerous, and not fit to be used for their intended purpose from Plaintiffs and the Class members, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

5840. Defendants were provided notice of the issues raised in this count and this Complaint by the FDA investigations, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Wyo. Stat. Ann. §40-12-109 to Defendants. Because Defendants failed to adequately remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

5841. Pursuant to Wyo. Stat. Ann. §40-12-108(a)–(b), Plaintiffs and the Class members seek an order enjoining Defendants' unfair or deceptive acts or practices and awarding damages and any other just and proper relief available under the Wyoming CPA.

COUNT 312
Strict Products Liability/Failure to Warn
(Against All Defendants)

5842. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5843. This cause of action is brought on behalf of the Wyoming Class (for the purpose of this section, "Class") against all Defendants.

5844. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and members of the Class, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Products and NDMA. These actions were under the ultimate control and supervision of Defendants.

5845. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs and members of the Class, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Products.

5846. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs and members of the Class of dangers associated with Ranitidine-Containing Products. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

5847. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Products.

5848. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing Products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products in the absence of such warnings and/or instructions.

5849. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety of, or to minimize the dangers to users and consumers, including

Plaintiffs and members of the Class, of their product and to those who would and did foreseeably use or be harmed by Defendants' Ranitidine-Containing Products.

5850. Even though Defendants knew or should have known that Ranitidine-Containing Products posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their drugs 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, and were not known to end users and consumers, such as Plaintiffs and members of the Class.

5851. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein. Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and physicians of the risks of exposure to their Ranitidine-Containing Products. Defendants failed to warn and wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Products. Defendants made false and/or misleading statements concerning the safety of Ranitidine-Containing Products.

5852. At all relevant times, the failure to provide these adequate warnings and/or instructions made Defendants' Ranitidine-Containing Products unreasonably dangerous.

5853. Without adequate warnings and/or instructions, the Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants and created risks to the health and safety of consumers which far outweigh their utility.

5854. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and members of the Class, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

5855. Plaintiffs and members of the Class used and/or were exposed to Defendants' Ranitidine-Containing Products without having knowledge of their dangerous characteristics.

5856. At all relevant times, Plaintiffs and members of the Class used and/or were exposed to the use of Defendants' Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes.

5857. Plaintiffs and members of the Class could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to, or at the time of, each Plaintiff and member of the Class consuming the drug. Plaintiffs and members of the Class, 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' Ranitidine-Containing Products.

5858. 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.

5859. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs and members of the Class to avoid using the drug. Instead, Defendants: (a) 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-Containing Products; (b) continued to aggressively promote the efficacy of their Ranitidine-Containing Products, even after they knew or should have known of the unreasonable risks from use or exposure; and (c) concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Products.

5860. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Products through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But, Defendants did not disclose these known risks through any medium.

5861. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs and members of the Class, 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 and members of the Class could not have averted their injuries.

5862. Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products was a substantial factor in causing Plaintiffs' injuries.

5863. As a result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5864. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5865. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 313
Strict Products Liability/Manufacturing Defect
(Against All Defendants)

5866. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5867. This cause of action is brought on behalf of the Wyoming Class (for the purpose of this section, "Class") against all Defendants.

5868. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Products ingested by Plaintiffs.

5869. At all relevant times, the medications ingested by Plaintiffs and members of the Class were expected to and did reach Plaintiffs and members of the Class without a substantial

change in their anticipated or expected condition as manufactured, handled, distributed, stored, and sold by Defendants.

5870. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5871. At all relevant times, the medications ingested by Plaintiffs and members of the Class were used in a manner that was foreseeable and intended by Defendants.

5872. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs and members of the Class.

5873. Defendants' Ranitidine-Containing Products are inherently dangerous and defective, unfit, and unsafe for their intended and reasonably foreseeable uses, and accordingly do not meet or perform to the expectations of ordinary consumers or health care providers.

5874. The Ranitidine-Containing Products ingested by Plaintiffs and members of the Class further contained manufacturing defects, in that they were not the bioequivalent to approved Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs and members of the Class.

5875. The Ranitidine-Containing Products create risks to the health and safety of consumers that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the Ranitidine-Containing Products because of Defendants' manufacturing defects, which included, but were not limited to:

(a) failure to follow cGMPs;

(b) failure to clean and test recovered and/or recycled solvents;

(c) failure to adequately inspect/test the drugs during the manufacturing process;

(d) failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; and

(e) failure to implement appropriate quality control systems, distribution, storage, and handling instructions and storage and distribution conditions for the active pharmaceutical ingredient and the finished drug.

5876. The manufacturing defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and Class members' injuries.

5877. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5878. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5879. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

COUNT 314
Strict Products Liability/Design Defect
(Against All Defendants)

5880. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 748 as though fully set forth herein.

5881. This cause of action is brought on behalf of the Wyoming Class (for the purpose of this section, "Class") against all Defendants.

5882. At all relevant times, Defendants engaged in the business of developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs and the Class members, thereby placing Ranitidine-Containing Products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, handled, stored, and distributed the Ranitidine-Containing Products used by Plaintiffs and the Class members, as described herein.

5883. At all relevant times, Defendants' Ranitidine-Containing Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

5884. At all relevant times, Defendants' Ranitidine-Containing Products reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs and the Class members, without substantial change in their anticipated and expected condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Products and aimed at a consumer market. Defendants

were, at all relevant times, involved in the retail and promotion of Ranitidine-Containing Products marketed and sold.

5885. At all relevant times, the medications ingested by Plaintiffs and members of the Class were shipped and stored in compliance with Defendants' express written instructions.

5886. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or distributors, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

5887. Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or distributors, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

5888. At all relevant times, Defendants knew or had reason to know that Ranitidine-Containing Products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

5889. Therefore, at all relevant times, Defendants' Ranitidine-Containing Products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

(a) Defendants' Ranitidine-Containing Products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

(b) Defendants' Ranitidine-Containing Products were not reasonably safe when used in a reasonably anticipated or intended manner;

(c) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to transform into the carcinogenic compound NDMA within the human body;

(d) Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Products and, specifically, the ability for Ranitidine-Containing Products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

(e) Defendants failed to provide accurate expiration dates on the product label;

(f) Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage and distribution of the drug;

(g) exposure to Ranitidine-Containing Products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

(h) Defendants knew or should have known at the time of marketing Ranitidine-Containing Products that exposure to Ranitidine-Containing Products could result in cancer and other severe illnesses and injuries;

(i) Defendants did not conduct adequate post-marketing surveillance of their Ranitidine-Containing Products; and

(j) Defendants could have employed safer alternative designs and formulations.

5890. Plaintiffs and the Class members used and/or were exposed to Defendants' Ranitidine-Containing Products without knowledge of Zantac's dangerous characteristics.

5891. At all times relevant to this litigation, Plaintiffs and the Class members used and/or were exposed to the use of Defendants' Ranitidine-Containing Products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

5892. Plaintiffs and the Class members could not reasonably have discovered the defects and risks associated with Ranitidine-Containing Products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking Ranitidine-Containing Products to cancer.

5893. The Ranitidine-Containing Products were more dangerous than an ordinary consumer and healthcare provider would expect when used as intended or in a manner reasonably foreseeable to Defendants.

5894. The harm caused by Defendants' Ranitidine-Containing Products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Ranitidine-Containing Products were and are more dangerous than alternative products, and Defendants could have designed Ranitidine-Containing Products to make them less dangerous. Indeed, at the time the Manufacturing Defendants designed Ranitidine-Containing Products, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation was attainable.

5895. At the time Ranitidine-Containing Products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Products. For example, Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Products, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

5896. The defects in Defendants' Ranitidine-Containing Products were substantial factors in causing Plaintiffs' and the Class members' injuries.

5897. As a direct and proximate result of Defendants' conduct described herein, Plaintiffs and members of the Class have been injured because they purchased a defective drug they otherwise would not have purchased, did not receive the benefit of the bargain, and/or suffered out-of-pocket loss.

5898. Accordingly, Plaintiffs and members of the Class would not have: (a) been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and (b) sustained a significantly increased risk of developing various types of serious and potentially deadly cancers.

5899. As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

IX. EXEMPLARY/PUNITIVE DAMAGES ALLEGATIONS

5900. Defendants' conduct, as described above, was wanton, willful, and malicious, and carried out with conscious, reckless, and flagrant disregard for the rights, health, welfare, and safety of others, including Plaintiffs and Class members. Defendants risked the lives of consumers and users of their products, including Plaintiffs and members of the Class, with full knowledge of, and deliberate and utter indifference to, Ranitidine-Containing Products' defects, the dangers they posed, and the harm that was substantially certain to result. Defendants' officers, directors, and/or managing agents authorized and participated in Defendants' practice of concealing the known risks and exposing unsuspecting purchasers and users of Ranitidine-Containing Products to excessive levels of NDMA, a known carcinogen, in defiance of the law, statutes, and regulations meant to govern Defendants' conduct and protect consumers.

5901. Since introducing Ranitidine-Containing Products to the market, Defendants made conscious decisions not to test, redesign, re-label, properly manufacture, warn, or inform the unsuspecting public, including Plaintiffs and Class members, of Ranitidine-Containing Products' unreasonably dangerous condition. Defendants concealed material facts and deliberately crafted their labels, marketing, and promotion to mislead consumers, knowing they could profit by convincing consumers that ranitidine was harmless to humans and that full disclosure of the true risks of ranitidine would limit the amount of money Defendants would make from selling the drug. Defendants' objective was accomplished not only through misleading labels, but through a comprehensive scheme of selective, misleading research and testing, false advertising, and deceptive omissions. While failing to take any reasonable steps to prevent harm, Defendants deliberately and persistently distributed Ranitidine-Containing Products and encouraged consumers of Ranitidine-Containing Products to unknowingly purchase and ingest carcinogenic NDMA through Defendants' products, all for Defendants' immense profit and enrichment.

5902. Accordingly, as provided by law, Defendants' willful, wanton, reckless, outrageous, and malicious conduct warrants an award of punitive or exemplary damages.

PRAYER FOR RELIEF

Plaintiffs, on behalf of themselves and the proposed 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 Class, appoint Plaintiffs as named representatives of the Class, and appoint Plaintiffs' counsel as Class counsel;

B. Enter judgment against Defendants and in favor of Plaintiffs and the Class;

C. Award damages (including actual, nominal, presumed, statutory, punitive, and treble damages as provided by law) and restitution to the Class in an amount to be determined at trial, plus interest, in accordance with law;

D. Order disgorgement of Defendants' profits;

E. Order any and all appropriate preliminary and/or final injunctive or equitable relief against the conduct of Defendants described herein;

F. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law;

G. Award such further and additional relief as is necessary to redress the harm caused by Defendants' unlawful conduct and as the Court may deem just and proper under the circumstances; and

H. Award any other relief that is deemed just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the Class(es), demand a trial by jury on all issues to triable.

DATED: June 22, 2020

Respectfully submitted,

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Plaintiffs' Leadership Development Committee

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2020, 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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