IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Ermelinda Arnold; David Wallace; Linda Kretzer, Individually and as Representative of the Estate of Ernest Kretzer, Deceased; Steven Hickey; Kenneth Johnsey; Stanley Skelton; Henry Williams, Individually and as Representative of the Estate of Cindy Williams, Deceased; Rondro Boney; Sheila Carter; John Hill; Tyler Koenig; Gina Metcalf; Tara Agosta; David A. Sugars; Maleia R. Fisher; Mary Sidel; Karen T. Anderson, Individually and as Representative of the Estate of Sydney Dunn, Deceased; Ann Darlene Moore, Individually and as Representative of the Estate of Timothy A. Moore, Deceased; Kevin Hill, Individually and as Representative of the Estate of Laurie Pudvah, Deceased; Terry Davis; Angelina Brown; Jonathan C. Brenton; Stephanie A. Caine; Victor J. McCurdy; Gino Iavarone; Maxine Silsel, Individually and as Representative of the Estate of Stephen Silsel, Deceased; Shela Villardi; Richard Griffin, Individually and as Representative of the Estate of Donna Bifano, Deceased; Aaron Lospennato; Kenneth L. Benn; Plaintiffs, **v.** **GlaxoSmithKline Holdings (Americas), Inc.; GlaxoSmithKline, LLC; Pfizer, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Sanofi-Aventis U.S. LLC; Sanofi U.S. Services, Inc.; Patheon Manufacturing Services, LLC; DSM Pharmaceuticals, Inc.;** Defendants.	**JURY TRIAL DEMANDED**

PLAINTIFFS' ORIGINAL COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiffs in the above-styled action (collectively "Plaintiffs"), by and through Plaintiffs' undersigned attorneys, and files this, Plaintiffs' Original Complaint and Demand for Jury Trial against the Defendants named herein and alleges as follows:

INTRODUCTION

1. Zantac is the branded name for ranitidine, a "blockbuster" drug sold to treat heartburn. For decades, Zantac and/or its generic equivalent ranitidine, were promoted by Defendants as a safe and effective treatment for heartburn.

2. Defendants had little incentive to investigate dangers in a product that was producing over $1 billion in annual sales. Instead, Defendants turned a blind eye to the fact that ranitidine transforms, over time and under particular conditions, into high levels of N-Nitrosodimethylamine ("NDMA"), a well-known cancer-causing compound. NDMA has no medicinal or beneficial purpose whatsoever: its only function is to cause cancer and its only use is to induce tumors in animals as part of laboratory experiments. The U.S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 96 nanograms. Yet, in a single dose of Zantac, researchers are discovering over 3 million nanograms of NDMA.

3. Eventually, in 2019, revelations by independent researchers that ranitidine transforms into NDMA, caused widespread recalls of Zantac and its generic equivalents. On April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable levels of NDMA accumulation.

4. Plaintiffs, upon information and belief, each regularly took various forms of brand name Zantac, including over the counter ("OTC") Zantac, and/or generic ranitidine products, including OTC ranitidine products. These products were manufactured and sold by Defendants or bore labels and warnings created and controlled by Defendants. Plaintiffs developed cancer as a result of taking ranitidine-containing drug product(s) that Defendants designed, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold. Plaintiffs bring this action seeking damages against the Defendants for causing Plaintiffs'

cancers.

PLAINTIFFS

5. Plaintiffs refer to the attached Exhibit A for description of the Judicial District and the State where Plaintiffs were residents that purchased and regularly took various forms of brand name Zantac, including over the counter ("OTC") Zantac, and where Plaintiffs were ultimately diagnosed with cancer.

6. Plaintiffs, upon information and belief, regularly took various forms of brand name Zantac, including over the counter ("OTC") Zantac, manufactured, and sold by Defendants. Plaintiffs developed cancer as a result of taking medication that Defendants designed, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold. Plaintiffs bring this action seeking damages against the Defendants for causing their cancers.

7. Due to Plaintiffs' use of the ranitidine-containing products identified herein, Plaintiffs have suffered and will continue to suffer significant harm, conscious pain and suffering, physical injury and bodily impairment, including cancer, permanent physical deficits, permanent bodily impairment, lost income, impairment of power to labor and earn money, and substantial medical expenses. Plaintiffs' injuries required, or will likely require, hospitalizations, surgeries, medication, and other therapies to address the physical effects and damage caused by Plaintiffs' use of ranitidine-containing drugs.

8. Had any Defendant warned that Zantac could lead to exposure to NDMA or, in turn, cancer, Plaintiffs would not have taken the ranitidine-containing drugs. Plaintiffs would not have taken ranitidine had Plaintiffs known of or been fully and adequately informed by Defendants, or by Plaintiffs' physicians, of the true increased risks and serious dangers of taking ranitidine-containing drugs.

9. Despite acting with reasonable diligence, Plaintiffs did not learn of the connection between ranitidine-containing products and Plaintiffs' cancer until a date within the applicable statute of limitations.

DEFENDANTS

Defendant GSK[1]

10. Defendant GlaxoSmithKline Holdings (Americas), Inc. is a Delaware corporation with its principal place of business located at 1105 N. Market Street, Suite 622, Wilmington, Delaware 19801. GlaxoSmithKline (America), Inc. is a citizen of Delaware.

11. Defendant GlaxoSmithKline, LLC is a Delaware corporation with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania 19112. Manufacturer Defendant GlaxoSmithKline, LLC's sole member is Manufacturer Defendant GlaxoSmithKline (America) Inc., a Delaware corporation with its principal place of business also in Delaware. GlaxoSmithKline, LLC is a citizen of Delaware.

Defendant Pfizer

12. 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 is a citizen of Delaware and New York.

Defendant Boehringer Ingelheim

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

[1] Defendants GlaxoSmithKline Holdings (Americas), Inc. and GlaxoSmithKline, LLC shall be collectively referred to as "GSK."

Defendant Sanofi [2]

14. 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 Defendant 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.

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

Defendant Patheon

16. Defendant Patheon Manufacturing Services, LLC ("Patheon") is a limited liability company organized under the laws of Delaware. DPI Newco, LLC is the sole member of Patheon Manufacturing Services, LLC. Thermo Fisher (CN) Luxembourg Holding S.a.r.l. is the sole member of DPI Newco, LLC. Thermo CIDTEC, Inc. and TFS Life Holding, LLC are the two members of Thermo Fisher (CN) Luxembourg Holding S.a.r.l. Thermo CIDTEC, Inc. is incorporated in New York and also maintains its principal place of business in New York. TFS Life Holding, LLC has five members:

(1) Thermo Fisher Scientific Life Technologies Investment UK I Limited, which is an English company; (2) Thermo Fisher Scientific Sweden Holdings, LLC;

(3) Thermo Fisher Scientific Investments (Sweden) S.a.r.l.; (4) Thermo Fisher Scientific Life Investments U.S. Financing II, LLC; and (5) TFS Group Holding II, LLC. Thermo Fisher Scientific Sweden Holdings, LLC has two members, Thermo Fisher Scientific Investments

[2] Sanofi U.S. Services, Inc. and Defendant Sanofi-Aventis U.S., LLC shall be collectively referred to as "Sanofi."

(Sweden) S.a.r.l. and TFS Group Holding II, LLC. Thermo Fisher Scientific Investments (Sweden) S.a.r.l. has two members, CHK Holdings, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSWH International Holdings, LLC. Fisher Scientific Worldwide Holdings, I C.V. is the sole member of FSWH International Holdings, LLC. Fisher Scientific Worldwide Holdings I C.V. has two members, Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSIR Holdings (U.S.), Inc. also a Delaware corporation with its principal place of business in Massachusetts.

17. TFS Group Holding II, LLC has two members, Thermo Fisher Scientific Life Investments C.V. and TFS Group Holding I, LLC. Thermo Fisher Scientific Life Investments C.V. has two members, Thermo Fisher Scientific Life Investments GP. LLC and Thermo Fisher Scientific Life Holdings II C.V., Thermo Fisher Scientific Life Holdings III C.V. is the sole member of Thermo Fisher Scientific Life Investments GP LLC. Thermo Fisher Scientific Life Holdings III C.V. has five members: (1) Thermo Fisher Scientific AL-1, LLC; (2) TFLP, LLC; (3) Thermo Fisher Scientific, Inc., a Delaware corporation with its principal place of business in Massachusetts; (4) Thermo BioAnalysis, LLC; and (5) Erie Scientific, LLC. TFLP, LLC is the sole member of Thermo Fisher Scientific AL-1, LLC. TFPL has five members: (1) Thermo Electron Corporation, a Delaware corporation with its principal place of business in Massachusetts; (2) Erie Scientific, LLC, whose sole member is Apogent Technologies, Inc., a Wisconsin corporation with its principal place of business in Massachusetts; (3) Apogent Technologies, Inc.; (4) Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts; and (5) Fisher WWD Holding, LLC, whose sole member is Fisher Scientific Worldwide, Inc., a Delaware

corporation with its principal place of business in Massachusetts. Thermo BioAnalysis, LLC has three members: (1) Thermo Fisher Scientific, Inc.; (2) Life Sciences International Limited, an English company; and (3) Life Sciences International, LLC, whose sole member is Helmet Securities Limited, an English company. TFS Group Holding I, LLC has twelve members: (1) Thermo Fisher Scientific, Inc.; (2) Thermo Luxembourg Holding, LLC (Thermo Luxembourg Holding S.a.r.l.), whose sole member is Thermo Fisher Scientific Germany BV & Co. KG, which is owned by Thermo Fisher Scientific, Inc. and Thermo Fisher Scientific Germany B.V., a Dutch company; (3) Molecular Bioproducts, Inc., a California corporation with its principal place of business also in California; (4) Thermo Fisher Scientific Investments (Sweden) S.a.r.l., which has two members, CHK Holdings, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSWH International Holdings, LLC, whose sole member is Fisher Scientific Worldwide Holdings I, C.V., whose members are Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSIR Holdings (U.S.), Inc., a Delaware corporation with its principal place of business in Massachusetts; (5) Fisher Scientific Worldwide Holdings I C.V.; (6) Thermo Fisher Scientific Life Investments U.S. Financing I, LLC, whose members are FSIR Holdings (U.S.), Inc. and FSWH International Holdings, LLC; (7) Fisher Scientific Worldwide, Inc.; (8) Fisher Clinical Services, Inc., a Pennsylvania corporation with its principal place of business also in Pennsylvania; (9) Liberty Lane Investment, LLC, whose sole member is FSIR Holdings (U.S.), Inc; (10) Fisher Scientific International, LLC, whose sole member is Thermo Fisher Scientific, Inc; (11) Thermo Fisher Scientific Life Investments U.S. Financing II, LLC, whose members are Perbio Science Sweden Holdings AB, a Swedish Company, and Thermo Fisher Scientific Life Investments II S.a.r.l., which is owned by Perbio Science AB, a Swedish

company; and (12) Erie LP Holding, LLC, whose sole member is Erie UK Holding Company, a Delaware corporation with its principal place of business in Massachusetts. Consequently, Patheon Manufacturing Services, LLC is a citizen of Pennsylvania.

18. Further, Patheon was, at times, engaged in the manufacture, distribution, labeling, packaging, handling, storage, transport and/or selling of OTC Zantac on behalf of Defendants Pfizer, BI and Sanofi from 1995 until it was withdrawn from the market due to unsafe levels of NDMA found in products. Patheon Manufacturing Services is a citizen of Delaware, New York, California, Massachusetts, Wisconsin and Pennsylvania.

19. Manufacturer Defendant DSM Pharmaceuticals, Inc. ("DSM") is a Delaware corporation with its principal place of business located at 5900 Martin Luther King Jr. Hwy., Greenville, North Carolina 27834. DSM Pharmaceuticals, Inc., was engaged at all times in the manufacture, distribution, labeling, packaging, handling, storage, transport and/or selling of OTC Zantac on behalf Defendant Patheon from 1995 until it was withdrawn from the market due to unsafe levels of NDMA found in its products.

20. Defendants GSK, Pfizer, Boehringer Ingelheim, Sanofi, Patheon and DSM, shall be referred to collectively as "Defendants." Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine-containing products, including the ranitidine-containing products ingested by Plaintiffs. Defendants have conducted business and derived substantial revenue from designing, manufacturing, marketing, handling, distributing, storing, and selling ranitidine-containing.

JURISDICTION & VENUE

21. This Court has jurisdiction over the subject matter of this action and the parties. DEL. CONSTIT. Art. IV, § 7.

22. The causes of action alleged in this Complaint arise out of or relate to the Defendants' contacts with Delaware. Substantial activities relating to the design, development, marketing, labeling, warnings, promotion and sales of ranitidine-containing products were performed by Defendants in Delaware.

23. This Court possesses general personal jurisdiction over each Defendant each Defendants was incorporated or licensed to conduct business in Delaware.

24. This Court has personal jurisdiction over Defendants pursuant to, and consistent with, Delaware's long-arm statute, Del. Code Ann. Tit. 10, § 3104, and the requirements of Due Process in so far that each Defendant committed one or more of the following:

a. Defendants transacted, and continue to transact, continuous and systematic business within the State of Delaware and regularly conduct business, receive substantial revenues, and sell products and perform services in the State of Delaware;

b. Defendants caused tortious injury in the State of Delaware by an act or omission in the State of Delaware;

c. Defendants have caused tortious injury in the State of Delaware or outside of the State of Delaware by acts or omissions outside the State of Delaware

-- by Defendants who regularly solicit business in the state of Delaware, engage in other persistent courses of conduct in Delaware or derive substantial revenue from services, or things used or consumed in the State of Delaware;

d. Defendants incorporated under the law of Delaware and registered to

conduct business in Delaware, thus expressly consenting to jurisdiction in Delaware;

e. Defendants have registered to conduct business in Delaware as thus consenting to jurisdiction in Delaware;

f. Defendants have an interest in, use or possess real property in the State of Delaware;

g. Requiring Defendants to litigate this claim in the State of Delaware does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

25. Defendants have sufficient minimum contacts with the forum state, Delaware, such that, "maintenance of the suit does not offend traditional notions of fair play and substantial justice." *International Shoe Co. v. Washington*, 326 U.S. 310 (1945).

26. Venue in this action properly lies in Delaware because all Defendants are incorporated in Delaware and are citizens of Delaware as alleged in this complaint.

27. This lawsuit is not subject to removal based on the existence of a federal question. Plaintiffs asserts common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1447(c).

28. This lawsuit is not subject to removal because Plaintiffs asserts claims against multiple forum defendants. All Defendants are citizens of Delaware as alleged herein. Defendants are therefore precluded from removing this civil action due to the presence of multiple forum defendants. 28 U.S.C. § 1441(b)(2) ("A civil action . . . may not be removed if any of the parties properly joined and served as defendants is a citizen of the State in which such action is brought.").

30. Additionally, even if removal were effected in contravention of 28 U.S.C. § 1441(b)(2), there is not subject matter jurisdiction within federal court because there is not complete diversity of citizenship between Plaintiffs and Defendants.

31. Plaintiffs seek relief that is within the jurisdictional limits of the Court.

FACTUAL ALLEGATIONS

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

32. Zantac (or ranitidine) was developed by GSK[3] in 1976. GSK, and specifically Glaxo Holdings, Ltd., developed ranitidine in response to the success of the then leading H2 blocker Tagamet (chemically known as cimetidine). The first ranitidine molecule patent was approved by the U.S. Patent and Trademark Office on December 5, 1978. The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

33. In 1983, the FDA granted approval to GSK to sell prescription Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product— a "blockbuster." Due in large part to GSK's marketing strategy, which emphasized the purported safety of the drug, Zantac became the first prescription drug in history to reach $1 billion in sales.

34. In 1993, GSK entered into a joint venture with Pfizer to develop an over-the-counter version of Zantac. Zantac OTC was approved through the NDA process in 1995 and

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

became available without a prescription.

35. Generic versions of Zantac (ranitidine) became available approximately in 1997. Although sales of brand-name Zantac declined as a result of generic and alternative products, Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million – a 3.1% increase from the previous year.

36. The times during which each Defendant controlled the Zantac NDA's and manufactured and sold branded Zantac pills are alleged below: [4]

Defendant	Prescription or OTC	Sale Start Date Year	Sale End Date Year
GSK	Prescription	1983	2019
Pfizer	OTC	1995	2006
Boehringer Ingelheim	OTC	2006	2019
Sanofi	OTC	2017	Present

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

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

[4] The dates a particular Defendant manufactured Zantac do not capture the entire time period that its version of Zantac was available for consumption. For example, a Zantac pill manufactured in 2016 likely takes months or years before it eventually reaches store shelves and then a consumer. Further, then, it could be an additional months or years before that particular pill was ingested by a consumer or Plaintiffs. Therefore, the mere fact that a Defendant ceased manufacturing Zantac in a given year does not absolve that Defendant from liability stemming from Plaintiffs' ingestion of Zantac in the following years.

original OTC Zantac product expired, generic manufacturers were allowed to sell OTC ranitidine.

39. FDA approved numerous generic manufacturers for the sale of prescription and OTC ranitidine through the abbreviated new drug application (ANDA) process. An ANDA contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand name drug it references. Generic drugs must be comparable to the branded drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use.[5]

40. The warnings and precautions on generic ranitidine are required by law to precisely match branded Zantac's warnings. Defendants are aware that healthcare providers, including physicians and pharmacists, rely upon the warnings and label information for Zantac when prescribing and filling prescriptions with generic ranitidine. A generic drug manufacturer can only change their generic drug's warning label after a brand manufacturer has done so. Thus, it was foreseeable that users of generic ranitidine products would be injured due to the inadequate warnings and instructions, and negligent misrepresentations contained on the Zantac labeling created and controlled by Defendants. As the innovators of Zantac and the Zantac labeling, Defendants are liable to Plaintiffs for injuries caused by generic ranitidine-containing drugs required by federal law to have the same label as Zantac.

II. THE DANGERS OF NDMA.

41. NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens. The dangers that NDMA poses to human health have long been recognized. A news article

published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[6] NDMA is no longer produced or commercially used in the United States, only a poison.

42. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.

43. The World Health Organization ("WHO") states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[7] The WHO has stated that scientific testing indicates that NDMA consumption is positively associated with either gastric or colorectal cancer and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

44. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[8] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[9]

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[5] https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

[6] Jane Brody, *Bottoms Up: Alcohol inmoderation can extend life,* THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water,* THE GLOBE AND MAIL CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA adducts in humans after exposure to methylatingagents,* 405MUTAT. RESEAR. 135 (1998)(notingthat"chronic exposure ofrats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellularcarcinomas), bile ducts, blood vessels and Kupffer cells").

except for research, such as a tumor initiator in certain animal bioassays. In other words, it is

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

[8] *Id.* at 3.

[9] *Id.*

45. The FDA considers NDMA a chemical that "could cause cancer" in humans.[10]

46. 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.

47. Most recently, beginning in the summer of 2018, several generic drugs used to treat high blood pressure and heart failure – valsartan, losartan, and irbesartan – were recalled because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

48. The FDA has established a permissible daily intake limit for the probable human carcinogen, NDMA, of 96 ng (nanograms). One filtered cigarette contains between 5-43 ng of NDMA. Recent testing shows that a single pill of ranitidine may contain staggering NDMA levels in excess of 3,000,000 ng.

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

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

51. In other long-term animal studies of mice and rats utilizing different routes of

[10] https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals- ndma-found-samples-ranitidine

exposures – inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) – cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

52. Overall, the animal studies demonstrate 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.

53. Pursuant to the EPA's cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."

54. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. While these studies (several discussed below) consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction – as little as 1 millionth – the exposures noted in a single Zantac capsule, i.e., 0.191 ng/day (dietary) v. 304,500 ng/day (Zantac).

55. 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 of NDMA.[11]

56. 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.[12]

57. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant

[11] Pobel et al, *Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in Marseille, France,*11 EUROP. J. EPIDEMIOL. 67-73 (1995).
[12] La Vecchia et al, *Nitrosamine intake and gastric cancer risk,* 4 EUROP. J. CANCER. PREV. 469-474 (1995).

elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 ng/day.[13]

58. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[14]

59. 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.[15]

60. 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.[16]

61. 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.[17]

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[13] Rogers et al, *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cancer,* 5 CANCEREPIDEMIOL. BIOMARKERS PREV. 29-36 (1995).
[14] Knekt et al, *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study,* 80 INT. J. CANCER 852-856 (1999).
[15] Straif et al, Exposure to high concentrations of nitrosamines and cancer mortality among a cohort of rubber workers, 57 OCCUP ENVIRON MED 180-187 (2000).
[16] Loh et al, N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)-Norfolk Study, 93 AM J CLIN NUTR. 1053-61 (2011).
[17] Zhu et al, *Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada,* 111 BR JNUTR. 6, 1109-1117 (2014).

62. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant cancers (i.e., not malignant), (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and

(3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

63. NDMA breaks down into various derivative molecules that, themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine, including colon.

64. Alarmingly, Zantac is in the FDA's category B for birth defects, meaning it is considered safe to take during pregnancy. However, in animal experiments, for those animals exposed to NDMA during pregnancy, the offspring had elevated rates of cancer in the liver and kidneys.

HOW RANITIDINE TRANSFORMS INTO NDMA.

65. The NDMA contained in ranitidine-containing products is not caused by any direct contamination. Rather, the ranitidine molecule, itself, contains the constituent molecules to form NDMA. That is, the high levels of NDMA produced by Zantac are inherent to the molecular structure of ranitidine, the active ingredient in Zantac. The ranitidine molecule contains both a nitrite ("NO3") and a dimethylamine ("DMA") group which are well known to combine to form NDMA. Thus, ranitidine produces NDMA by "react[ing] with itself," which means that *every dosage and form of ranitidine,* including Zantac, exposes users to NDMA.

66. The formation of NDMA by the reaction of DMA and a nitroso source (such as

a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply.[18] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants were specifically linked to the presence of ranitidine.[19]

67. Ranitidine leads to NDMA exposure by: (1) formation of NDMA in the human stomach; (2) formation of NDMA due to an enzymatic reaction throughout the human body; and (3) formation of NDMA due to heat, humidity, and time.

Formation of NDMA in the Environment of the Human Stomach.

68. At the time that ranitidine was developed, there was scientific literature suggesting that drugs like ranitidine, which contain a dimethylamine ("DMA") group within the molecule, are highly likely to form NDMA, when combined with other substances (i.e., nitrate) already found in the body. Indeed, nitrate is not only naturally found in the body, but bacteria and enzymes in the body reduce the nitrates (NO3) found in food into nitrites (NO2-). In addition, many foods and preservatives contain nitrates. Glaxo scientists should have known that human physiology and diet would lead to the development of NDMA in the human body after the ingestion of ranitidine.

69. In 1981, the very year Zantac was launched commercially outside of the United States, two exchanges in *The Lancet* — one of the most widely read and respected medical and scientific publications — discussed the potential toxicity of cimetidine and ranitidine. Cimetidine, also an H2 blocker, has a similar chemical structure to ranitidine.

70. Dr. Silvio de Flora, and Italian researcher from the University of Genoa, wrote

[18] Ogawa et al, *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney,* 264 J. BIO. CHEM. 17, 10205-10209 (1989).
[19] Mitch et al, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review,* 20 ENV. ENG, SCI. 5, 389-404 (2003).

about experiments he had conducted regarding cimetidine and ranitidine in human gastric fluid. When ranitidine was exposed to gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects [.]"[20] Dr. de Flora hypothesized that these effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." Concerned with these results, Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals, or by giving inhibitors of nitrosation such as ascorbic acid."

71. GSK responded to Dr. de Flora's concern.[21] A group of GSK researchers specifically noted they were "obviously concerned as to whether or not a mutagenic N-nitroso derivative of ranitidine could be formed in the stomach." Apparently, GSK was fully aware of the potential NDMA issue. GSK acknowledged that in the presence of nitrites, a "N-nitroso nitrolic acid derivative was formed" that was "mutagenic [.]" GSK, however, dismissed this finding because the levels of nitrate used were much higher than what would be expected to occur after a meal, and, therefore, any N-nitroso compound found would not likely occur in a person in real world experiences. GSK asserted that "no mutagenic nitrosated product of ranitidine is likely to be formed in man under any conceivable physiological conditions [.]"

72. In 1983, the same year Zantac was approved in the United States, seven researchers from the University of Genoa published a study discussing the nitrosation of ranitidine and its genotoxic effects (ability to harm DNA).[22] The researchers concluded:

[20] De Flora, *Cimetidine, Ranitidine, and Their Mutagenic Nitroso Derivatives*, THE LANCET 993-994 (Oct. 31, 1981).
[21] Brittain et al, *The Safety of Ranitidine*, THE LANCET 1119 (Nov. 14, 2981).
[22] Maura et al, *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOX. LTTRS. 97- 102 (1983).

> [I]t appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of including damage in mammalian cells. […] These findings are consistent with those of Dr. de Flora, who showed that preincubation of ranitidine with excess nitrite in human gastric juice resulted in mutagenic effects.

73. Then, again in 1983, Dr. de Flora, along with four other researchers, published the complete findings.[23] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine [.]" Id. Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals […] Absorbic acid has been proposed as an inhibitor of nitrosation combined with nitrosatable drugs and appears to block efficiently the formation of mutagenic derivatives from […] ranitidine." *Id.*

74. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[24] 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 which supply many American cities with water.

75. These studies did not appreciate the full extent of NDMA formation risk from

[23] De Flora et al, *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).
[24] Le Roux et al, *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism,* 46 *Environ. Sci. Technol.* 20, 11095-11103 (2012)

ranitidine; specifically, the added danger of this drug having not only a labile, or easily broken down, DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing of NDMA levels in ranitidine batches (*e.g*. see discussion of Valisure testing, *infra)* are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

76. Antacid drugs are known to increase stomach pH and thereby increase the growth of nitrite-reducing bacteria which further elevate levels of nitrite. This fact is well known and even present in the warning labels of antacids like Prevacid (lansoprazole) and was specifically studied with ranitidine in the original approval of the drug. Thus, higher levels of nitrites in patients regularly taking Zantac would be expected.

77. In fact, NDMA formation in the stomach has been a concern for many years, and ranitidine has been specifically implicated as a cause of NDMA formation by multiple research groups, including those at Stanford University.

78. Existing research shows that ranitidine interacts with nitrites and acids in the chemical environment of the human stomach to form NDMA. In vitro tests demonstrate that when ranitidine undergoes "nitrosation" (the process of a compound being converted into nitroso derivatives) by interacting with gastric fluids in the human stomach, the byproduct created is dimethylamine ("DMA") — which is an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA, a secondary N-nitrosamine.

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

79. 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.

80. 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]."[25]

81. Computational modelling demonstrates that ranitidine can readily bind to the DDAH-1 enzyme in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA").

82. 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.

83. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, stomach, bladder, brain, colon, 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, including the bladder.

84. 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

[25] Ogawa et ai *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney,* 264J. *BIO. CHEM* 17, 10205-10209 (1989).

barrier, within 1-2 hours. When the 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.

B. Formation of NDMA by Exposure to Heat and/or Time.

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

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

87. The researchers cautioned:

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

88. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks

down into NDMA, accumulating over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real-a point underscored by the FDA's swift removal of the product from the market.

89. The FDA has acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.

90. Indeed, the FDA's recent testing confirms that NDMA levels increase in ranitidine even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures to which ranitidine may be exposed during distribution and handling by retailers.[26]

91. Testing by Emery Pharma indicates on samples of Zantac products produced to it by GlaxoSmithKline, Boehringer Ingelheim, and Sanofi showed, on average, 1,530 ngs for each 150 mgs of ranitidine. For unexpired product, their testing revealed 1,096.6 ngs for each 150 mgs of ranitidine.

IV. DEFENDANTS KNEW OF THE NDMA DEFECT BUT FAILED TO ADEQUATELY ADDRESS OR WARN ABOUT KNOWN RISKS.

92. During the time that Defendants manufactured, distributed, transported, stored, and sold ranitidine-containing products in the United States, the weight of scientific evidence showed that ranitidine-containing products exposed users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug's label - or through any other means - and Defendants failed to report these risks to the FDA or to the public.

[26] Press Release, *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market*, U.S. Food and Drug Administration (April 1, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-requests- removal-all-ranitidine- products-zantac-market

A. Defendants Knew or Should Have Known That Ranitidine-Containing Products Exposed Users to Unsafe Levels of NDMA and Posed A Cancer Risk.

93. Going back as far as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested. Numerous studies and publications revealed the dangers of NDMA and the presence of NDMA in ranitidine-containing products. [See Facts, s*upra* at II).

94. Defendants knew of the scientific studies revealing the dangers of ranitidine. For instance, GSK knew of Dr. de Flora's publication because GSK responded in the Lancet. GSK claimed that the level of nitrite needed to induce the production of NDMA were not likely to be experienced by people in the real world. GSK dismissed Dr. de Flora's testing results as not having "practical clinical significance."

95. 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. 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 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 only expected to use ranitidine- containing products for a short-term period:

> The importance of this finding is not clear. High levels of nitrate 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.

96. 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.

97. In addition to the numerous epidemiology studies examining how NDMA causes cancer in humans, there is also evidence directly linking ranitidine exposure to cancer.

98. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[27]

99. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk of breast cancer, an effect that was even more pronounced in those with specific gene mutations.[28]

100. In another comprehensive epidemiological study looking at various cancer risks and H2 blockers, including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[29] Of particular note, the study indicated that people under the age of 60 that took ranitidine were five times more likely to contract prostate cancer.

101. Yet another study, published in 2018, demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other histamine type 2 receptor

[27] D. Michaud, et al, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPI. BIOMARK. & PREV. 250–254, 252 (Feb. 2004).
[28] Robert W. Mathes, et al, *Relationship between histamine2-receptor antagonist medications and risk of invasive breast cancer*, 17 CANCER EPI. BIOMARKERS & PREVENTION 1, 67-72 (2008).
[29] Laurel A. Habel, et al, *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 PHARMACOEPIDEMOLOGY & DRUG SAFETY 149-155 (2000).

antagonists (H2RAs) 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 and, more significantly, did not study or consider long term use of H2RAs or the possibility of a dose dependent increase in risk.[30]

102. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H2RAs.[31] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H2RAs as a confounder. The study only considered use of H2RAs within one year of cancer diagnosis and still found an increased odds ratio associated with use of H2RAs and hepatocellular carcinoma, a type of liver cancer.

103. In addition, Memorial Sloan Kettering recently tested ranitidine for cancer association. In January 2021, a Sloan Kettering paper demonstrated an association with cancer that showed a "significant increase" in the odds of developing multiple types of cancer.

104. Based on the available scientific evidence, Defendants each knew or should have known of the dangers of both ranitidine-containing products and NDMA to consumers such as Plaintiffs.

B. Defendants Failed to Adequately Warn Physicians, Patients, and the Public About the NDMA Risk.

105. 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," 21 C.F.R. § 201.5, and conform to requirements governing the appearance of the

[30] 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 PHARMA & THERAP 1, 55-64 (2018).
[31] Shao, Y-HJ, et al., *Association between proton pump inhibitors and the risk of hepatocellular carcinoma*, 48 ALIMENTARY PHARMA & THERAP 4, 460-468 (2018).

label. 21 C.F.R. § 801.15.

106. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[32] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising. 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."[33] If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded. 21 C.F.R. § 201.6; 201.10. Because Defendants did not disclose NDMA as an ingredient in the ranitidine-containing products ingested by Plaintiffs, the subject drugs were misbranded. It is unlawful to introduce a misbranded drug into interstate commerce. Thus, the ranitidine-containing products ingested by Plaintiffs were unlawfully distributed and sold.

54. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like Zantac to the agency's attention. Defendants disregarded the scientific evidence available to them and did not report to the FDA significant new information affecting the safety or labeling of Zantac. Defendants did not propose a disclosure that would warn healthcare providers and patients of the link between ranitidine and NDMA.

55. Defendants also never disclosed the relevant studies to the public, nor did they publicly disclose the link between ranitidine and NDMA.

[32] 21 C.F.R. § 801.15; 65 Fed. Reg. 14286 (March 16, 2000).
[33] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).

56. In a 1981 study published by GSK, the innovator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[34] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiffs believe this was intentional – a gambit by the manufacturer to avoid detecting a carcinogen in their product.

57. Indeed, in that same year, Dr. de Flora published a note in *The Lancet* discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites — a substance commonly found in food and in the body. Defendants were aware of this as GSK specifically responded to the note and attempted to discredit it. Notwithstanding this legal risk signal, GSK did not test for this alarming cancer risk, and it did so intentionally.

58. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[35]

This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. 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. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine

[34] Carey et al, *Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography,* 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).

[35] Thomas et al, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents,* 6 *GUT.* Vol. 28, 726-738 (1987).

would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk. In fact, on information and belief, none of the Defendants 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 its trials associated with the ranitidine NDA. This is because when using mass spectrometry, it requires heating of up to 130 °C which can result in excessive amounts of nitrosamines being formed. Had the Defendants used a mass spectrometry assay, the results would have revealed large amounts of NDMA, and the FDA would never have approved Zantac as being safe.

54. There are multiple alternatives to Zantac that do not pose the same risk, such as Cimetidine (Tagamet), Famotidine (Pepcid), Omeprazole (Prilosec), Esomeprazole (Nexium), and Lansoprazole (Prevacid).

C. Defendants Failed to Notify the FDA About the Presence of NDMA in Ranitidine-Containing Products.

55. Manufacturers 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.

56. 21 C.F.R. § 314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

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

57. 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.

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

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

60. 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 Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products from the market.

C. Defendants Failed to Adhere to Proper Manufacturing and Storage Practices.

61. Defendants stored Zantac products in preparation for their sale.

62. Under federal law, a drug shall be deemed to be adulterated if (1) it consists in whole or in part of any filthy, putrid or decomposed substance, 21 U.S.C. § 351(a)(1), (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health, 21 U.S.C. § 351(a)(2)(A), or (3) if the drug, or the facilities or controls used for its manufacture, processing, packaging or holding, do not conform with "Current Good Manufacturing Practices" ("CGMPs") to assure that such drug meets requirements as to safety, quality, purity, identity, and strength characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

63. 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.

64. 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.

65. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.

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

67. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

68. Defendants could dictate and control the conditions under which Zantac, in both its API and finished dose forms) were transported, packaged and stored. Yet, Defendants failed to ensure that their ranitidine-containing products were kept safely from excessive heat and humidity.

69. Defendants were aware of the dangers of exposing Ranitidine- Containing Drugs to excess heat– given available scientific information and the fact that each Zantac *box* states, "to avoid excessive heat" and to keep the drug below 77°F.

70. Yet, despite knowledge that NDMA could form in ranitidine by exposure to heat and/or over time in storage. No Defendants, upon information and belief, took action to

reduce this risk through altering supply-chain conduct or warning consumers.

71. Had Defendants provided appropriate storage and transportation warnings, distributors or sellers of a Ranitidine-Containing Drug would be duty- bound to follow the handling procedures and ensure the product is not exposed to dangerous heat or humidity conditions.

D. Defendants failed to adequately test ranitidine-containing drugs for NDMA.

72. Defendants knew or should have known of the risk and dangers of NDMA formation and bore a responsibility to properly investigate the issue. None did.

73. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[36] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiffs believes this was intentional — a gambit by the manufacturer to avoid detecting a carcinogen in their product.

74. Indeed, that same year, Dr. de Flora had published a note in The Lancet discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly found in food and in the body. GSK was clearly aware of Dr. de Flora's study – because GSK responded to the note – yet, GSK did not undertake appropriate testing for NDMA in ranitidine-containing drugs.

75. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically

[36] Carey, *et al*., *Determination of ranitidine and its metabolites in human urine by reversed- phase ion-pair high-performance liquid chromatography*, 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).

investigating gastric contents in human patients and N-nitroso compounds.[37] This study specifically indicated that there were no elevated levels of N- nitroso compounds (of which NDMA is one). However, the study was rigged to fail. 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. Furthermore, in addition to this approach being less accurate, 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." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk. The inadequacy of this test was knowable in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of this study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

54. Upon information and belief, none of the Defendants 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 their trials associated with the ranitidine NDA. That is because when using mass spectrometry, it requires heating of up to 130 degrees Celsius, which can result in excessive amounts of nitrosamines being formed. Had the Defendants used a mass spectrometry assay, it would have revealed in the finding of large amounts of NDMA, and the FDA would never have approved Zantac as being safe.

V. THE VALISURE STUDY REVEALS HIGH LEVELS OF NDMA IN ZANTAC.

[37] Thomas, *et al*., *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 *GUT*. Vol. 28, 726-738 (1987).

55. Valisure, LLC ("Valisure") is an online pharmacy that also runs an analytical laboratory that is accredited by the International Organization for Standardization ("ISO") — an accreditation recognizing the laboratories technical competence for regulatory compliance. 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.

56. As part of its testing of Zantac, and other ranitidine products, in every lot tested, Valisure discovered exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY 19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[38] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

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

150 mg Tablets or equivalent	**Lot#**	**NDMA per tablet (ng)**
Reference Powder*	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	791800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006

[38] US Food and Drug Administration. (updated 01/25/2019). Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, *FY*19-005-DPA-S.

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

57. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at **28,000 times** the legal limit. In terms of smoking, a person would need to smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

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

59. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in

foods like processed meats and is elevated in the stomach by antacid drugs. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[39]

60. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present.

Table 2 – Valisure Biologically relevant tests for NDMA formation

Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid	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

61. Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA allowable limit. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 ng level (over 7,000 for the 50 μg level).

[39] *See, e.g.,* https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; https://youtu.be/jzS2kuB5_wg; https://youtu.be/Z3QMwkSUIEg ; https://youtu.be/qvh9gyWgQns.

VI. ZANTAC AND RANITIDINE-CONTAINING PRODUCTS ARE PULLED FROM THE MARKET.

62. On September 13, 2019, in response to the citizen's petition filed by Valisure, LLC, U.S. and European regulators stated that they are reviewing the safety of ranitidine.

63. On September 18, 2019, Novartis AG's Sandoz Unit, which makes generic drugs, stated that it was halting the distribution of its versions of Zantac in all markets while Canada requested drug makers selling ranitidine to stop distribution. On September 28, 2019, CVS Health Corp. stated that it would stop selling Zantac and its own generic ranitidine products out of concern that it might contain a carcinogen. Walmart, Inc., Walgreens Boot Alliance, and Rite Aid Corp. also removed Zantac and ranitidine products.

64. On October 2, 2019, the FDA stated that it was ordering all manufacturers of Zantac and ranitidine products to conduct testing for NDMA and that preliminary results indicated unacceptable levels of NDMA so far.

65. On November 1, 2019, the FDA released its preliminary results, showing unsafe levels of NDMA in various ranitidine products, including Zantac.

66. At no time did any Defendant attempt to include a warning about NDMA or any cancer, nor did the FDA ever reject such a warning. Defendants had the ability to unilaterally add an NDMA and/or cancer warning to the Zantac label (for both prescription and OTC). Had any Defendant attempted to add an NDMA warning to the Zantac label (either for prescription or OTC), the FDA would not have rejected it.

VII. EXEMPLARY/ PUNITIVE DAMAGES ALLEGATIONS.

67. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of Zantac,

particularly the carcinogenic potential of Zantac as it transforms into NDMA within the chemical environment of the human body. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers.

68. This was not done by accident or through some justifiable negligence. Rather, Defendants knew that it could turn a profit by convincing consumers that Zantac was harmless to humans, and that full disclosure of the true risks of Zantac would limit the amount of money Defendants would make selling Zantac. Defendants' object was accomplished not only through their misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this Complaint. Plaintiffs were denied the right to make an informed decision about whether to purchase and use ranitidine-containing drugs, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

69. Accordingly, Plaintiffs request punitive damages against Defendants for the harms caused to Plaintiffs.

TOLLING, DISCOVERY RULE, FRAUDULENT CONCEALMENT, ESTOPPEL

70. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including estoppel, equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

71. The expiration of any applicable statute of limitations has been tolled pursuant to a tolling agreement.

72. Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Zantac. Defendants had a duty to disclose the true character, quality, and nature of Zantac because this was non-public information over

which Defendants continue to have control. Defendants knew that this information was not available to Plaintiffs, Plaintiffs' medical providers, and/or health facilities, yet Defendants failed to disclose the information to the public, including to the Plaintiffs.

73. The discovery rule applies to toll the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of the facts that Plaintiffs had been injured, the cause of Plaintiffs' injuries, and the tortious nature of the wrongdoing that caused the injuries.

74. The expiration of any applicable statute of limitations has been equitably tolled by reason of Defendants' misrepresentations and concealment. Through affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiffs the true risks associated with use of Zantac. Due to Defendants' acts and omissions, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its degradation into NDMA. Plaintiffs' physicians did not warn Plaintiffs of the true risks of ingesting Zantac including the increased risk of cancer. During the limitations period, Plaintiffs could not reasonably have known or learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

75. Within the time period of any applicable statute of limitations, Plaintiffs could not have discovered through the exercise of reasonable diligence that exposure to Zantac is injurious to human health. Plaintiffs' physicians did not warn Plaintiffs that the true risks of ingesting NDMA in ranitidine included the increased risk of cancer. Plaintiffs did not discover and did not know of facts that would cause a reasonable person to suspect the risk associated with the use of Zantac, nor would a reasonable and diligent investigation by Plaintiffs have

disclosed that Zantac would cause Plaintiffs' illnesses.

76. Despite acting with reasonable diligence, Plaintiffs did not learn of the link between Plaintiffs' cancers and ranitidine exposure until a time within the statute of limitations for filing of Plaintiffs' claim.

CAUSES OF ACTION

COUNT I NEGLIGENCE - DESIGN

77. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

78. Defendants directly or indirectly, caused Zantac and other generic ranitidine-containing products to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiffs. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Zantac within the State of Delaware and throughout the United States.

79. At all relevant times, Defendants had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging, sale, and distribution of Zantac, 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 ranitidine-containing drug products.

80. Defendants' duty of care owed to consumers, healthcare providers and the general public included providing accurate, true, and correct information concerning the risks of using ranitidine-containing products, the risks of improper storage and exposure to heat and humidity, and appropriate, complete, and accurate warnings concerning the potential adverse effects of ranitidine-containing products. In particular, Defendants owed a duty of care to

consumers, healthcare providers and the general public to provide accurate, true and correct information concerning ranitidine's ability to degrade into the carcinogenic compound NDMA under certain conditions.

81. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine and, specifically, the carcinogenic properties of NDMA when these products were ingested.

82. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of ranitidine-containing drugs could cause Plaintiffs' injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers were unaware of the risks and the magnitude of the risks associated with use of ranitidine-containing drug products.

83. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, storage, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of ranitidine-containing products. Defendants manufactured and produced defective Zantac which carries 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 a user's or consumer's storage and handling and use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

84. Defendants were negligent in their promotion of Zantac, outside of the labeling context, by failing to disclose material risk information as part of their promotion and

marketing of Zantac, including the internet, television, print advertisements, etc. Nothing prevented Defendants from being honest in their promotional activities, and, in fact, Defendants had a duty to disclose the truth about the risks associated with Zantac in their promotional efforts, outside of the context of labeling.

85. Readily available testing methods revealed the dangers of Zantac and ranitidine-containing products. For example, gas chromatography-mass spectrometry, the technique Valisure employed in 2019 to identify NDMA forming in ranitidine, was a widely available, cost-effective, industry-standard testing method. If this testing method had been used by Defendants to test Zantac and ranitidine, they could have determined that Zantac and ranitidine transforms into NDMA when subjected to heat.

86. No Defendant tested the effects of temperature, time, humidity, light, or other relevant storage or transportation conditions on the quantity of NDMA in ranitidine-containing products.

87. Testing of the ranitidine molecule at any time would have revealed that hotter temperatures, longer time periods, and higher humidity each increases the amount of NDMA.

88. Testing of the ranitidine molecule at any time also would have revealed that the typical temperature, time-period, and humidity that ranitidine-containing products were exposed to before being consumed resulted in dangerously high levels of NDMA.

89. Defendants knew or should have known that ranitidine-containing products posed a grave risk of harm. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they designed,

manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the product, but were not known to end users and consumers, such as Plaintiffs.

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

91. Defendants also were on notice of the need to test and fully evaluate the carcinogenicity of ranitidine based on the research by Dr. de Flora and GSK scientists performed in the 1980s, which would have alerted a reasonable manufacturer of Zantac and/or ranitidine to beware of the potential for NDMA to form in the drug and/or in the human body.

92. Any of a variety of tests for NDMA would have sparked quick action. The FDA initiated a voluntary recall only seven months after Valisure first publicized its NDMA testing results in September 2019. If any Manufacturer Defendant had performed and publicized a similar test at an earlier time, the FDA and broader market would have acted as quickly and decisively as happened in 2019, since the dangerous properties of NDMA were widely understood at all relevant times.

93. Defendants, directly or indirectly, manufactured, labeled, packaged, tested, and/or sold ranitidine-containing products that were used by Plaintiffs.

94. Defendants had a duty to warn Plaintiffs of the risk of cancer from exposure to NDMA in Zantac.

95. Defendants had a duty to impose safe expiration dates and storage conditions that would decrease the risk of harm to Plaintiffs. None did.

96. At all relevant times, Defendants had reason to know of the need for testing to reveal the hazards and dangers of Zantac and ranitidine and, specifically, the carcinogenic

properties of NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored based on studies conducted in the 1980s. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings and instructions of the risk and safe expiration and storage conditions, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of ranitidine-containing products.

97. Defendants' negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Zantac without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Zantac while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Zantac and the carcinogenic potential of NDMA as created in the human body as a result of ingesting Zantac or other ranitidine-containing products, and, consequently, the risk of serious harm associated with human use of Zantac or other ranitidine-containing products;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not ranitidine-containing products were safe for their intended consumer use;

d. Failing to test ranitidine for NDMA, both from degradation over time in

storage and transport conditions and due to chemical reactions in the human body.

e. Failing to use reasonable and prudent care in testing, research, manufacture, storage, transport and development of ranitidine-containing products so as to avoid the risk of serious harm associated with the prevalent use of ranitidine-containing products;

f. Failing to design and manufacture Zantac so as to ensure it was at least as safe and effective as other medications on the market intended to treat the same symptoms;

g. Failing to ensure that ranitidine-containing products did not contain, in whole or in part, filthy, putrid or decomposed substance, 21 U.S.C. § 351(a)(1);

h. Preparing, packing or holding ranitidine-containing products under unsanitary conditions whereby it may have been rendered injurious to health, 21 U.S.C. § 351(a)(2)(A),

i. Failing to ensure that facilities or controls used for the manufacture, processing, packaging or holding, conformed with "Current Good Manufacturing Practices" ("CGMPs") to assure that such drug meets requirements as to safety, quality, purity, identity, and strength characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

j. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would

use ranitidine- containing products;

k. Failing to select a container system that would reduce the levels of humidity to which ranitidine was exposed. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods of time after the seal is broken – causing the remaining units to be exposed to humidity which produces NDMA. Placing each unit of ranitidine in a blister pack, or a similar individually packaged container, would ensure humidity control until the consumer used each unit. Alternatively, reducing the number of units of ranitidine in each bottle would subject each unused unit of ranitidine to humidity for a shorter period of time because consumers would purchase new, sealed, bottles more frequently.

l. Failing to disclose to Plaintiffs, users/consumers, healthcare providers and the general public that use of ranitidine-containing products presented significant risks of cancer and other grave illnesses;

m. Failing to warn Plaintiffs, consumers, and the general public that ranitidine- containing products' risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiffs and other consumers;

n. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of ranitidine-containing products;

o. Representing that their 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 the products' labeling or other promotional materials that would alert consumers and the general public of the risks;

q. Advertising, marketing, and recommending the use of the 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 NDMA in ranitidine-containing products;

r. Continuing to disseminate information to their consumers, which indicate or imply that Defendants' products are not unsafe for regular consumer use;

s. Continuing the manufacture and sale of their products with the knowledge that the products were unreasonably unsafe and dangerous; and

t. Shipping, storing, and handling, or allowing for the shipping, storing and handling of, ranitidine-containing products in a manner that subjected it to heat and humidity so that it generated high levels of NDMA.

98. Defendants knew and/or should have known that foreseeable consumers, such as Plaintiffs, would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, storage, transport, and sale of ranitidine- containing products.

99. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

100. Defendants' negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendants' negligence, Plaintiffs would not have developed cancer.

101. Defendants' conduct, as described above, was reckless and without regard for the safety of consumers including Plaintiffs herein. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiffs of the risk of cancer from NDMA in Zantac, including warning or informing of appropriate conditions under which to store their products, the appropriate expiration dates, and the significant risks of seemingly harmless behavior such as storing ranitidine in a bathroom medicine cabinet where it would be regularly exposed to humidity.

102. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of Zantac, particularly its carcinogenic potential as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage. Nonetheless, Defendants deliberately crafted their label and marketing to mislead consumers, including consumers of generic ranitidine- containing products that used the same label as Zantac. This was not done accidentally or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that ranitidine-containing products were harmless to humans, and that full disclosure of the true risks would limit the amount of money Defendants would make selling the drugs. Defendants' objective was accomplished not only through a

misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiffs were denied the right to make informed decision about whether to purchase and use ranitidine-containing products, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

103. Defendants' conduct, as described above, was willful, wanton, malicious and conducted with reckless disregard for the health and safety of users of Zantac products, including Plaintiffs. Defendants' conduct warrants an award of punitive damages.

104. As a direct and proximate result of Defendants negligently placing defective ranitidine-containing products into the stream of commerce, Plaintiffs suffered significant, serious, and permanent injury and Plaintiffs sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court. There was also a measurable and significant interval of time during which Plaintiffs suffered great mental anguish and other personal injury and damages. Further, Plaintiffs sustained a loss of income, and loss of earning capacity.

COUNT II NEGLIGENCE—FAILURE TO WARN

105. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

106. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or

humidity.

107. NDMA is a potent carcinogen in humans. Higher exposure to NDMA over longer time periods leads to even higher risks of cancer.

108. To mitigate degradation of ranitidine into NDMA in the stomach, over time, and in the presence of heat or humidity, consumers should have been warned:

a. To consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g. not in a bathroom). No ranitidine containing product contained this warning.

b. To consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of ranitidine.

c. Not to take ranitidine with or after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.

d. To take ranitidine with Vitamin E or Vitamin C to inhibit nitrosation and the formation of NDMA in the stomach. No ranitidine-containing product contained this warning.

109. Defendants knew or should have known about each of these risks in time to warn consumers.

110. Defendants should have considered ranitidine's propensity to degrade into NDMA over time, and in the presence of heat or humidity, when setting the expiration and/or retest dates for their ranitidine-containing drugs. Instead, ranitidine-containing products had expiration dating periods of one or two years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that

ranitidine contained far lower levels of NDMA when consumed.

111. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

112. In setting the expiration and/or retest dates for their ranitidine-containing drugs, Defendants were also required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166. Storage conditions must account for conditions including the storage container, heat, light, humidity and other factors.

113. Defendants failed to adhere to their duties to set accurate expiration dates based upon stability testing that complied with manufacturers' duties to account for real-world conditions. These actions were under the ultimate control and supervision of Defendants.

114. A manufacturer has a duty of reasonable care to provide an adequate warning about known risks. The risk posed from NDMA in ranitidine was known and/or knowable by the Defendants. Defendants' duty of care owed to consumers and the general public included the duty 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 and, in particular, its ability to transform into the carcinogenic compound NDMA. Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

115. Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

116. At all relevant times, Defendants negligently designed, manufactured, tested,

marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

117. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine-containing products and, specifically, the carcinogenic properties of NDMA when ranitidine is ingested. Defendants knew or should have known about each of these risks in time to warn consumers.

118. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine- containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they manufactured, marketed, distributed, supplied, or sold the products, but were not known to end users and consumers, such as Plaintiffs.

119. Defendants negligently failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

120. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of Zantac because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such

products.

121. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of the Zantac label.

122. At all relevant times, Defendants negligently failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Zantac or another generic ranitidine-containing drug required to use the same formulation and label as Zantac.

123. Each Manufacturer Defendant breached this duty for the ranitidine-containing products it manufactured, marketed, and sold. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored or transported under humid conditions, when stored or transported under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture. Plaintiffs and/or his doctors would have read and heeded these warnings. As a result, Plaintiffs would not have ingested the ranitidine-containing drug(s) and would not have developed cancer or otherwise been harmed by exposure to NDMA in these products.

124. Despite this ability, Defendants failed to warn of the risks of NDMA in the warnings and precautions section of their ranitidine-containing products' label.

125. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics. Plaintiffs could not have reasonably discovered the risks associated with ranitidine-containing products prior to or at the time Plaintiffs

consumed the drugs. Plaintiffs and Plaintiffs' physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using ranitidine- containing products.

126. At all relevant times, Plaintiffs used and/or were exposed to ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

127. 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. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine- containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Zantac or other ranitidine-containing products.

128. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with ranitidine-containing products on the

warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of developing cancer and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert Plaintiffs' injuries.

129. Defendants' conduct, as described above, was reckless.

130. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

131. Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their ranitidine-containing products' labels were a substantial factor in causing Plaintiffs' injuries.

132. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs were injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to, past and future medical expenses, lost income, and other damages.

COUNT III:

NEGLIGENCE – MANUFACTURE, STORAGE AND TRANSPORTATION

133. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

134. Defendants manufactured ranitidine-containing products and transported

ranitidine-containing products from their facilities to distributor warehouses, as well as storing finished drug products in their facilities. Some Defendants also purchased API, which they store at their facilities.

135. Without limitation, examples of the manner in which Defendants breached their duty to exercise reasonable care in manufacturing ranitidine-containing drugs, included:

a. Failure to follow Good Manufacturing Practices;

b. Failure to adequately inspect/test the drugs during the manufacturing process;

c. Failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Drugs; and

d. Failure to implement appropriate handling instructions and storage conditions for the drug.

136. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of their product.

137. Upon information and belief, Defendants caused ranitidine-containing products to be exposed to excessive levels of heat and/or humidity during manufacture, storage, shipping, holding and handling that violated the instructions on the finished products' labels and caused ranitidine to degrade more quickly thereby increasing the levels of NDMA in the product.

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

139. Defendants were aware of the need to maintain sensitive pharmaceutical drugs

under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Defendants and pharmaceutical transportation companies are well aware of the importance of precise temperature control down to the degree, and advertise on their ability to provide precise, quality service. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

140. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has significantly more NDMA when tested.

141. NDMA forms due to chemical reactions in the human body, and also from degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and humidity is causing differing amounts of NDMA to form.

142. Different ranitidine-containing products listed slightly different storage and transportation requirements.

143. Defendants' systematically exposed ranitidine to excessive levels of heat and humidity that violated the instructions on the products' labels.

144. Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and humidity requirements on product labels. This failure led to widespread noncompliance.

145. For example, Defendants shipped ranitidine-containing products through the mail.

This method of transportation—whether through the United States Postal Service or large

common carriers such as FedEx and UPS—does not guarantee controlled temperature or humidity. Because of Defendants' choice to use or allow this method of transportation, ranitidine-containing products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid.

146. Defendants, directly or indirectly, transported, stored, handled, set the storage and transportation requirements for, and/or sold the ranitidine-containing products that were used by Plaintiffs.

147. At all relevant times, Defendants had a duty to exercise reasonable care with regard to the storage and transportation requirements for ranitidine-containing products to ensure the products were not unreasonably dangerous to foreseeable consumers and users.

148. Defendants breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

149. At all relevant times, Defendants knew or should have known of the need for storing and transporting ranitidine-containing products within the labeled temperature range and at low humidity. Yet, Defendants ignored this risk. They did not ensure ranitidine-containing products were stored at low humidity or within the temperature range on the label. Instead, some ranitidine was subjected to excessive humidity and heat during storage, transportation, and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA. Ignoring the risks of NDMA forming was unreasonable and reckless.

150. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

151. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

152. As a direct and proximate result of Defendants' failure to store and transport ranitidine-containing products properly (and to instruct or warn others handling ranitidine-containing products on how to store and transport them safely), Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

153. As a direct and proximate result of Defendants' systematic failures, excessive levels of NDMA formed in the ranitidine-containing products consumed by Plaintiffs. These high levels of NDMA caused Plaintiffs' injuries.

COUNT IV:

NEGLIGENT MISREPRESENTATION

154. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

155. At all relevant times, Defendants designed, manufactured, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, stored, handled, warehoused, distributed, sold and/or otherwise placed ranitidine containing drugs into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed ranitidine-containing drugs, such as Plaintiffs.

156. Defendants were negligent, reckless, and careless and owed a duty to Plaintiffs to make accurate and truthful representations regarding Ranitidine Containing Drugs, Defendants breached their duty, thereby causing Plaintiffs to suffer harm.

157. Defendants represented to Plaintiffs via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that:

a. Ranitidine-containing drugs were both safe and effective for the lifetime of the product, when in fact, the drug contains unsafe levels of NDMA far in excess of the 96-ng limit that increases as the product ages;

b. Consumption of Ranitidine-containing drugs would not result in excessive amounts of NDMA being formed in their bodies; and

c. The levels of NDMA in ranitidine-containing drugs have no practical clinical significance; and

d. Ranitidine-containing drugs were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

158. These representations were false. Because of the unsafe levels of NDMA in Ranitidine-containing drugs, the drug presented an unacceptable risk of causing cancer. Ranitidine-containing drugs are so unsafe that the FDA was compelled to order the immediate ban of all ranitidine-containing drugs on April 1, 2020.

159. Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

160. Defendants had a duty to accurately provide this information to Plaintiffs. In concealing this information from Plaintiffs, Defendants breached their duty. Defendants also gained financially from, and as a result of their breach.

161. Defendants intended for Plaintiffs to rely on these representations.

162. Plaintiffs reasonably relied on these representations and was harmed as

described herein. Plaintiffs' reliance on Defendants' representation was a substantial factor in causing Plaintiffs' harms. Had Defendants told Plaintiffs the truth about the safety and composition of Ranitidine-Containing Drugs, Plaintiffs would not have consumed or purchased them.

163. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiffs as to whether to purchase or consume Ranitidine Containing Drugs.

164. Defendants have yet to correct these misrepresentations about ranitidine-containing drugs.

165. Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.

166. Plaintiffs were injured as a direct and proximate result of Defendants' negligent misrepresentations regarding ranitidine-containing drugs as described herein.

COUNT V

STRICT LIABILITY – DESIGN DEFECT

167. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

168. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

169. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, stored, sold, and distributed the ranitidine-containing products used by Plaintiffs, as described herein.

170. At all relevant times, Defendants' ranitidine-containing products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this State and throughout the United States, including Plaintiffs, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

171. Defendants' ranitidine-containing products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants were defective in design because they were unreasonably dangerous, and did not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. Defendants' ranitidine-containing products were therefore unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

172. At all relevant times, Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold 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 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 stability of ranitidine and 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 package their ranitidine-containing products in a manner which would have preserved the safety, efficacy, quality, and purity of the product;

g. 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 of the drug;

h. Defendants knew or should have known at the time of marketing ranitidine- containing products that exposure to ranitidine could result in cancer and other severe illnesses and injuries;

i. Defendants did not conduct adequate post-marketing surveillance of their ranitidine-containing products;

j. Defendants did not conduct adequate stability testing of their product to ascertain shelf life, expiration, and proper storage, heat, and light specifications;

k. Defendants' ranitidine-containing products were adulterated in that they contained, in whole or in part, filthy, putrid or decomposed substance, 21 U.S.C. § 351(a)(1);

l. Defendants' ranitidine-containing products were adulterated in that they were prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health, 21 U.S.C. § 351(a)(2)(A),

m. Defendants' ranitidine-containing products were adulterated in that the drug, or the facilities or controls used for its manufacture, processing, packaging or holding, do not conform with "Current Good Manufacturing Practices" ("CGMPs") to assure that such drug meets requirements as to safety, quality, purity, identity, and strength characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

n. Defendants failed to select a container system that would reduce the levels of humidity to which ranitidine was exposed. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods of time after the seal is broken – causing the remaining units to be exposed to humidity which produces NDMA. Placing each unit of ranitidine in a blister back, or a similar individually packaged container,

would ensure humidity control until the consumer used each unit. Alternatively, reducing the number of units of ranitidine in each bottle would subject each unused unit of ranitidine to humidity for a shorter period of time because consumers would purchase new, sealed, bottles more frequently.

o. Defendants could have employed safer alternative designs and formulations.

173. At all relevant times, Defendants knew or had reason to know that Zantac products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

174. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products. Despite this ability, Defendants failed to warn Plaintiffs of the risks of NDMA and in the warnings and precautions section of their ranitidine-containing products' label.

175. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

176. Plaintiffs used and were exposed to Defendants' ranitidine-containing products without knowledge of Zantac's dangerous characteristics.

177. At all times relevant to this litigation, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products in an intended or reasonably foreseeable manner without knowledge of ranitidine's dangerous characteristics.

178. Plaintiffs 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 to cancer.

179. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering 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 Defendants designed ranitidine- containing products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

180. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could and would have avoided the risk of developing cancer and could and would have obtained alternative medication.

181. Defendants' defective design of ranitidine-containing products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Zantac products, including Plaintiffs. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine- containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

182. The defects in Defendants' ranitidine-containing products were substantial and

contributing factors in causing Plaintiffs' injuries, and, but for Defendants' misconduct and omissions, Plaintiffs would not have sustained injuries.

183. As a direct and proximate result of Defendants placing their defective ranitidine- containing products into the stream of commerce, and the resulting injuries, Plaintiffs sustained personal injuries, mental anguish, loss of income, loss of earning capacity, pecuniary loss, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT VI

STRICT LIABILITY – FAILURE TO WARN

184. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

185. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing products which are defective and unreasonably dangerous to consumers; including Plaintiffs, because they do not contain adequate warnings or instructions concerning the proper expiration date of the product nor the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

186. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, stored, transported, sold, and/or otherwise released into the stream of commerce Zantac products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs, and therefore had a continuing duty to warn of the risks associated with the use of ranitidine-containing drugs.

187. Defendants also had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as the packaging,

storage and handling or ranitidine.

188. Defendants, as a manufacturer, seller, or retailer of pharmaceutical medications, are held to the knowledge of an expert in the field.

189. At the time of manufacture, Defendants could have provided 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.

190. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their Zantac products' label.

191. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, promote the safety of, or minimize the dangers to users and consumers of their ranitidine-containing products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products, including Plaintiffs.

192. Even though Defendants knew or should have known that ranitidine posed a grave and unreasonable risk of harm, they failed to exercise reasonable care to investigate, study, test and warn of the dangerous risks associated with ranitidine use and exposure. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they manufactured, distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiffs.

193. To mitigate degradation of ranitidine into NDMA over time, and in the presence

of heat or humidity, consumers should have been warned to consume ranitidine shortly after manufacturing. No ranitidine-containing product contained this warning.

194. In fact, ranitidine-containing products had expiration dating periods of one or two years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

195. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

196. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166.

197. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn consumers (i.e., the reasonably foreseeable users) of the risks of exposure to their products. Defendants have wrongfully concealed information concerning the dangerous nature of ranitidine- containing products, the potential for ingested ranitidine to transform into the carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of ranitidine-containing products.

198. At all relevant times, Defendants' ranitidine-containing products reached the intended consumers, handlers, and users, or other persons coming into contact with these products within this State and throughout the United States, including Plaintiffs, without

substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

199. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

200. At all relevant times, Plaintiffs used Defendants' ranitidine-containing products for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

201. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed them. Plaintiffs relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

202. 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.

203. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to utilize the products safely and with adequate protection. Instead, Defendants: disseminated information that was inaccurate, false, and misleading; failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of their 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.

204. This alleged failure to warn is not limited to the information contained on ranitidine-containing products' labeling. The Defendants should have disclosed the known risks associated with Zantac and 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. Defendants were able, in accordance with federal law, to comply with relevant state law by providing a short expiration dating period that would accurately warn consumers not to consume ranitidine after significant portions of it had progressively deteriorated into NDMA.

205. Defendants are liable to Plaintiffs for injuries caused by their negligent, willful or reckless conduct, as described above. Defendants risked the lives of consumers and users of their products, including Plaintiffs, by consciously deciding not to warn or inform physicians, patients and the public of known safety problems associated with ranitidine-containing products.

206. Had Defendants provided adequate warnings, instructions and expiration dates and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication.

207. As a direct and proximate result of Defendants placing their defective ranitidine- containing products into the stream of commerce, and the resulting injuries, Plaintiffs sustained personal injuries, mental anguish, loss of income, loss of earning capacity,

pecuniary loss, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT VII:

BREACH OF EXPRESS WARRANTIES

208. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

209. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

210. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of ranitidine-containing products, including ranitidine syrup, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects;

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to ranitidine, when making representations to the FDA, consumers and the general public, including Plaintiffs; and

d. set proper expiration dates and storage temperatures and disclose the adverse consequences should ranitidine not be stored properly.

211. As alleged throughout this pleading, the ability of Defendants to properly

disclose those risks associated with its drugs are not limited to representations made on the labeling.

212. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that ranitidine-containing products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted its 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 its ranitidine-containing products would conform to the representations.

213. These express representations 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. Defendants knew and/or should have known that the risks expressly included in the warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that its brand OTC ranitidine tablets were safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective as consumer medication.

214. The representations about brand OTC ranitidine tablets, as set forth 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.

215. Defendants placed brand OTC ranitidine tablets into the stream of commerce

for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the ingestion of improperly stored ranitidine.

216. Defendants breached these warranties because, among other things, ranitidine products 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 warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that its products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with improper storage and handling of use ranitidine; and

b. Defendants represented that its products were safe for use and intentionally concealed information that demonstrated that ranitidine, by transforming into NDMA when improperly stored or handled, had carcinogenic properties, and that its products, therefore, were not safer than alternatives available on the market.

217. Plaintiffs detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of ranitidine in deciding to purchase the product. Plaintiffs reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of its products if not stored, shipped and handled properly. Plaintiffs would not have purchased ranitidine-containing products had Defendants properly disclosed the risks associated with the products, either through advertising, labeling, or any other form of

disclosure.

218. Defendants had sole access to material facts concerning the nature of the risks associated with their 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 its warnings and labels were inadequate and inaccurate.

219. Plaintiffs had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning ranitidine.

220. Plaintiffs used and/or were exposed to ranitidine as manufactured, tested, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

221. Had the labels, advertisements, or promotional material for its products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

222. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs have sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

223. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiffs suffered great mental anguish and other personal injury and damages.

224. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiffs sustained a loss of income and/or loss of earning capacity.

COUNT VIII FRAUD

225. Plaintiffs incorporate by reference each allegation of this Complaint as if fully stated herein.

226. Defendants intentionally and/or recklessly misrepresented to Plaintiffs materials facts regarding the safety and effectiveness of ranitidine.

227. Defendants knew or should have known through the exercise of due care that these representations were false yet made the deceitful representations to Plaintiffs.

228. Defendants actively concealed information about the defects and dangers of ranitidine with the absence of due care such that Plaintiffs and the consuming public would rely on such information, or the absence of information, in selecting ranitidine as a treatment.

229. The maker's knowledge of the falsity of the representation fundamentally supplies the element of "fraudulent utterance" required to make a misrepresentation actionable.

230. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiffs, to take their ranitidine products.

231. Plaintiffs justifiably relied on and/or were induced by Defendants' intentional or reckless misrepresentations and/or intentional or reckless failures to disclose the dangers of ranitidine and relied on the absence of information regarding the dangers which Defendants intentionally or recklessly suppressed, concealed, or failed to disclose to Plaintiffs' detriment.

232. As a direct and proximate result of the foregoing misrepresentations and deceitful intentions, Plaintiffs sustained serious injuries of a personal and pecuniary nature. Plaintiffs suffered serious injuries, including cancer and permanent disability and disfigurement. As a direct and proximate result of the foregoing misrepresentations and deceitful intentions,

Plaintiffs require and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses. Plaintiffs will also require additional medical and/or hospital care, attention, and services in the future.

COUNT IX SURVIVAL ACTIONS

233. Plaintiffs incorporate by reference each and every allegation of this Complaint as if fully stated herein.

234. Plaintiffs, as Administrators of the Estates of Decedents, beneficiaries of Decedents, and/or lawful representatives of Decedents, bring this claim on behalf of their Decedents' Estates and in their own rights for damages under any and all applicable statutes or common law.

235. As a direct proximate result of the actions of the Defendants, Plaintiffs' Decedents were forced to endure great conscious pain and suffering, impairment of the enjoyment of life, mental anguish, depression, ongoing psychological stress and other psychological damage, fear of impending death and other torment before Decedents' deaths.

236. As a direct and proximate result of the actions of the Defendants, Plaintiffs' Decedents incurred expenses for medical and treatment. In some instances, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates.

237. As a direct and proximate result of the actions of the Defendants, Plaintiffs' Decedents suffered a loss of earnings and loss of earning capacity.

238. As a direct and proximate result of the conduct of Defendants, Decedents, and their family members and/or beneficiaries, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and of social relationships.

239. A claim against Defendants for damages sufficient to compensate Decedents for their pain and suffering, mental anguish, medical expenses, loss or earnings and earning capacity, and harm to familial social relationships has survived to Plaintiffs as the Administrators of the Estates of Decedents, beneficiaries or Decedents, and/or lawful representatives of Decedents. Under applicable Wrongful Death statutes and common law, Decedents' Estates are entitled to damages including: damages for Decedents' pain and suffering, mental anguish, medical expenses, loss or earnings and earning capacity, depression, psychological stress and damage, and harm to Decedents' familial and social relationships.

240. As a direct and proximate result of the conduct of Defendants and including the observances of the suffering of the Decedents, until the dates of their deaths, Plaintiffs suffered permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs were also deprived of expected pecuniary benefits and contributions of support and services that would have been received from Decedents absent their deaths. Plaintiffs are entitled to compensatory damages under applicable Wrongful Death statutes and common law.

241. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Decedents, Plaintiffs and the public. Defendants acted maliciously and/or intentionally disregarded Decedents' and Plaintiffs' rights so as to warrant the imposition of punitive damages.

COUNT X WRONGFUL DEATH

242. Plaintiffs incorporate by reference each and every allegation of this Complaint as if fully stated herein.

243. Plaintiffs, as Decedents' spouses, next of kin, beneficiaries, and/or lawful

representatives of Decedents' Estates, bring this claim on behalf of themselves and as the Decedents' lawful beneficiaries.

244. As a result of the death of Decedents, Plaintiffs have been deprived of the expectation of pecuniary benefits which would have resulted from the continued life of Decedents, have lost contributions for support, companionship, society and household services, have incurred funeral expenses, and have suffered and will continue to suffer severe mental anguish.

245. As a direct and proximate result of the conduct of Defendants and the defective nature of ranitidine-containing products as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

246. As a direct and proximate result of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths.

247. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiffs' rights so as to warrant the imposition of punitive damages.

JURY TRIAL DEMAND

248. Plaintiffs demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests the Court to enter judgment in Plaintiffs' favor and against all Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;

c. pre-judgment and post-judgment interest;

d. costs including reasonable attorneys fees, court costs, and other litigation expenses; and

e. any other relief the Court may deem just and proper.

Date: December 20, 2022

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Counsel for Plaintiffs

EXHIBIT A
LIST OF 30 PLAINTIFFS

PLAINTIFF'S NAME AND CITY, STATE.

Plaintiff Ermelinda Arnold is a resident citizen of Corpus Christi, TX.
Plaintiff David Wallace is a resident citizen of Louisville, KY.
Plaintiff Linda Kretzer, Individually and as Representative of the Estate of Ernest Kretzer, Deceased, is a resident citizen of St. Joseph, MO.
Plaintiff Steven Hickey is a resident citizen of Spring, TX.
Plaintiff Kenneth Johnsey is a resident citizen of Terry, MS.
Plaintiff Stanley Skelton is a resident citizen of Red Banks, MS.
Plaintiff Henry Williams, Individually and as Representative of the Estate of Cindy Williams, Deceased, is a resident citizen of Smith Grove, KY.
Plaintiff Rondro Boney is a resident citizen of Wilmington, NC.
Plaintiff Sheila Carter is a resident citizen of Mount Airy, NC.
Plaintiff John Hill is a resident citizen of Greer, SC.
Plaintiff Tyler Koenig is a resident citizen of Salt Lake City, UT.
Plaintiff Gina Metcalf is a resident citizen of Chipley, FL.
Plaintiff Tara Agosta is a resident citizen of Pittsfield, ME.
Plaintiff David A. Sugars is a resident citizen of Chester, NE.
Plaintiff Maleia R. Fisher is a resident citizen of Raymond, WA.
Plaintiff Mary Sidel is a resident citizen of Cambridge, MD.
Plaintiff Karen T. Anderson, Individually and as Representative of the Estate of Sydney Dunn, Deceased, is a resident citizen of Hastings, FL.
Plaintiff Ann Darlene Moore, Individually and as Representative of the Estate of Timothy A. Moore, Deceased, is a resident citizen of Victoria, TX.
Plaintiff Kevin Hill, Individually and as Representative of the Estate of Laurie Pudvah, Deceased, is a resident citizen of Winooski, VT.
Plaintiff Terry Davis is a resident citizen of Madison, WI.
Plaintiff Angelina Brown is a resident citizen of Waldorf, MD.
Plaintiff Jonathan C. Brenton is a resident citizen of Interlachen, FL.
Plaintiff Stephanie A. Caine is a resident citizen of Searcy, AR.
Plaintiff Victor J. McCurdy is a resident citizen of Burleson, TX.
Plaintiff Gino Iavarone is a resident citizen of Beaufort, SC.
Plaintiff Maxine Silsel, Individually and as Representative of the Estate of Stephen Silsel, Deceased, is a resident citizen of Coral Gables, FL.
Plaintiff Shela Villardi is a resident citizen of Palm City, FL.
Plaintiff Richard Griffin, Individually and as Representative of the Estate of Donna Bifano, Deceased, is a resident citizen of Green Cove Springs, FL.
Plaintiff Aaron Lospennato is a resident citizen of Beverly, MS.
Plaintiff Kenneth L. Benn is a resident citizen of Jacksonville, FL.